**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

TERI MATHISON, ET AL.,

Plaintiffs,

v. CIVIL ACTION NO. 2:13-cv-05851

BOSTON SCIENTIFIC CORPORATION,

Defendant.

**MEMORANDUM OPINION AND ORDER**
**(*Daubert* Motions)**

Pending before the court are the following motions brought by the defendant: (1) Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. [Docket 36]; (2) Motion to Exclude the Opinions and Testimony of Michael Thomas Margolis, M.D. [Docket 37]; (3) Motion to Exclude the Opinions and Testimony of Jerry Blaivas, M.D. [Docket 39]; (4) Motion to Exclude the Opinions and Testimony of Ron Luke, JD, Ph.D. [Docket 40]; (5) Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. [Docket 42]; (6) Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D. [Docket 43]; (7) Motion to Exclude the Opinions and Testimony of Bruce Rosenzweig, M.D. [Docket 44]; (8) Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. [Docket 45]; (9) Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [Docket 49]; (10) Motion to Exclude the Opinions and Testimony of Richard Trepeta, M.D. [Docket 50]; and (11) Motion to Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [Docket 55].

Also pending before the court are the following motions brought by the plaintiffs: (1)

Motion to Exclude the Opinions and Testimony of Lonny S. Green, M.D. [Docket 46]; (2) Motion to Exclude the Opinions and Testimony of Christine Brauer, Ph.D. [Docket 47]; (3) Motion to Exclude the Opinions and Testimony of Gary L. Winn, Ph.D. [Docket 48]; (4) Motion to Exclude the Opinions and Testimony of Stephen Spiegelberg, Ph.D. [Docket 54]; and (5) Motion to Exclude the Opinions and Testimony of Stephen Badylak, D.V.M., Ph.D., M.D. [Docket 56].

My rulings are set forth below.

## I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 72,000 cases currently pending, approximately 16,000 of which are in the Boston Scientific Corporation ("BSC") MDL, MDL No. 2326. In this particular case, the plaintiff, Teri Mathison, was surgically implanted with the Obtryx Transobturator Mid-Urethral Sling System ("Obtryx"), a mesh product manufactured by BSC to treat SUI. Ms. Mathison received her surgery at Park Ridge Health in Fletcher, North Carolina, on June 28, 2007. (Short Form Compl. [Docket 1], at 4). She now claims that as a result of the implantation of the Obtryx, she has experienced various complications and injuries. The plaintiffs advance the following claims against BSC: negligence; strict liability for design defect, manufacturing defect, and failure to warn; breach of express and implied warranties; discovery rule, tolling, and fraudulent concealment; and punitive damages. (*Id.* at 4-5). The plaintiff's husband, Norman Mathison, also brings a claim for loss of consortium. (*Id.* at 5). The parties have retained experts to render opinions regarding the elements of these causes of action, and the instant motions involve the

parties' efforts to exclude or limit the experts' opinions pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

## II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if the expert is "qualified . . . by knowledge, skill, experience, training, or education," and if his testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) "based upon sufficient facts or data"; and (3) "the product of reliable principles and methods" that (4) have been reliably applied "to the facts of the case." Fed. R. Evid. 702. The Supreme Court has established a two-part test to govern the admissibility of expert testimony under Rule 702—the evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything to the court. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He or she must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.*

The district court is the gatekeeper. It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999), and *Daubert*, 509 U.S. at 588, 595). In carrying out this role, I "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md.*

*Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

*Daubert* mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94). Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("[T]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.") (citation omitted); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, the second part of the analysis, *Daubert* further explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

*Daubert*, 509 U.S. at 591–92 (internal citations and quotation marks omitted).

Ultimately, the district court has broad discretion in determining whether to admit or

exclude expert testimony, and the "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

## III. Preliminary Matters

Before I review these motions, I begin by addressing a few preliminary matters that affect many of the *Daubert* motions. First, both parties consistently challenge experts' opinions as improper state-of-mind or legal-conclusion testimony. As I have maintained throughout these MDLs, I will not permit the use of experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's knowledge, state of mind, or whether a party acted reasonably. *See, e.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding expert opinions on the defendant's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics). The reasonableness of conduct and a party's then-existing state of mind "are the sort of questions that lay jurors have been answering without expert assistance from time immemorial," and therefore, these matters are not appropriate for expert testimony. *Kidder v. Peabody & Co. v. IAG Int'l Acceptance Grp., N.V.*, 14 F. Supp. 2d 391, 404 (S.D.N.Y. 1998); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.").[1] Likewise, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). An expert may not state his opinion using "legal terms of art," such as "defective,"

[1] On a related note, I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his opinions—assuming the opinions are otherwise admissible—he may not be offered solely as a conduit for corporate information. There is no reason why the plaintiffs require an expert to opine on such facts.

"unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

I have diligently applied these rules to previous expert testimony, and I continue to adhere to them in this case. This does not mean, however, that each objection to state-of-mind or legal-conclusion testimony raised in these motions is valid. But I will not parse the numerous reports and thousand-page depositions for each expert to determine the validity of these same objections. Instead, the onus is on counsel to tailor expert testimony at trial in accordance with the above directive. Therefore, unless otherwise necessary, the remainder of this opinion does not address objections brought against an expert based on improper state-of-mind or legal-conclusion testimony.

I also note that several of the *Daubert* motions concern expert opinions entirely unrelated to the individual plaintiffs at bar. For example, some experts have opined on general and specific causation with the specific causation portion of the opinion pertaining to wave plaintiffs other than Ms. Mathison. In addition, the parties filed a total of *sixteen Daubert* motions involving, in many instances, duplicative experts. In an effort to remedy this problem of blanketed, duplicative *Daubert* motions, I directed the parties to file disclosures, indicating who, out of the sixteen challenged experts, they plan to call at trial for each case. (*See* Pretrial Order # 121 [Docket 57], at 5–6). Through these disclosures, I hoped to gain a better understanding of the particular arguments at issue, thereby refining my *Daubert* rulings for the benefit of the transferor judge. Rather than aiding the court in this endeavor, however, the parties have effectively ignored my pretrial order, identifying fifteen of the sixteen challenged experts as probable expert witnesses. (*See* BSC's Disclosure Required by Pretrial Order # 121 [Docket 58]; Pls.' Disclosure Required by Pretrial Order # 121 [Docket 59]). Without guidance from the parties to the contrary, I have

thus limited my review of the *Daubert* motions to only those arguments and opinions related to the instant plaintiffs. In other words, I disregard arguments included in the briefing directed exclusively at other wave plaintiffs and, consequently, irrelevant to Ms. Mathison's case.

Finally, I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __ (S.D. W. Va. 2014), *available at* 2014 WL 5320566; *Eghnayem v. Boston Scientific Corp.*, __ F. Supp. 3d __ (S.D. W. Va. 2014), *available at* 2014 WL 5461991. The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of an expert's opinion based on its reliability and relevance. In other words, the parties have comparatively examined each expert's opinions and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsel's expectations that I align with these previous rulings when faced with a different record are remiss, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper of expert testimony, as well as my duty to "respect[] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to entertain *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert opinions and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular opinions and objections currently before me, I assess "whether the reasoning or

methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the opinions contained therein.

Having addressed these preliminary matters, I now turn to BSC's *Daubert* motions.

## IV. BSC's *Daubert* Motions

In this case, BSC seeks to limit or exclude the expert opinions of Drs. Thomas H. Barker, Michael Thomas Margolis, Jerry Blaivas, Ron Luke, Jimmy W. Mays, Peggy Pence, Bruce Rosenzweig, Russell Dunn, Scott Guelcher, Richard Trepeta, and Vladimir Iakovlev.

### A. Thomas H. Barker, Ph.D.

The plaintiffs offer Dr. Barker as a biomaterials expert. He seeks to testify as to general opinions, such as those related to the biocompatibility of polypropylene mesh, mesh degradation, scar formation, mesh design, and mesh testing. (*See* Ex. D, Barker Report [Docket 36-4], at 4–7). BSC argues that Dr. Barker's opinions are unreliable because he lacks sufficient scientific support and because his opinions are litigation driven. BSC also contends that Dr. Barker is unqualified to opine on polypropylene generally and on design and testing. In forming his opinions, Dr. Barker relied upon the scientific literature, his experience, and corporate documents. (*See id.* at Ex. B (relied-upon list)).

#### 1. Reliability

##### *a. Opinion on a Mechanical Mismatch Between Mesh and the Human Body*

Dr. Barker opines that there is a mechanical mismatch between vaginal tissue and BSC mesh. (*See, e.g.*, Ex. D, Barker Report [Docket 36-4], at 5). I find this opinion to be unreliable. In

comparing the elastic moduli of vaginal tissue to that of mesh in order to support his opinion as to a mismatch, Dr. Barker relied on a study finding 6 to 7 kilopascals for vaginal tissue. (Ex. E, Barker Dep. (Dec. 15, 2014) [Docket 36-5], at 84:13–16). However, he admits that he has no scientific basis for forming a kilopascal number for BSC mesh. (*Id.* at 105:3–14). Moreover, Dr. Barker admits that, although "[t]here's significant evidence in the medical literature that there are regimes that the mesh is not mechanically matched with vaginal tissue . . . the studies were never done, so we can't say for sure." (*Id.* at 108:10–22). He also testifies that "there's certainly data to suggest that the mesh gets significantly stiff under load" but then concedes that, "without proper testing, it's everyone's guess." (*Id.* at 111:13–14). Such an opinion rests on an unreliable basis. To the extent that Dr. Barker merely opines that vaginal tissue and polypropylene mesh are not composed of the same material, such an opinion is not helpful to a jury. Dr. Barker's opinion that a mechanical mismatch exists is **EXCLUDED**.

*b. Opinions on the Clinical Significance of His Mechanical Performance Findings*

Dr. Barker's opinions on the clinical consequences resulting from the alleged mechanical mismatch between the mesh and the human body are **EXCLUDED** as unreliable as well. (*See, e.g.*, Ex. D, Barker Report [Docket 36-4], at 6–7). His opinion on the mechanical mismatch generally is excluded, and, thus, any derivative opinions of such are also unreliable. Dr. Barker testified that testing would need to be done in order to determine the effect that an implant may have in vivo. (*See* Ex. E, Barker Dep. (Dec. 15, 2014) [Docket 36-5], at 97:21–1). However, he also states that no one has performed this testing for transvaginal mesh. (*See id.* at 98:2–7). Concluding that mesh degrades, deforms, or causes scarring in the human body based on speculation that there is a mechanical mismatch between vaginal tissue and BSC mesh fails to survive *Daubert* scrutiny. Moreover, in forming these in vivo opinions, Dr. Barker relied on a

mesh study performed ex vivo, where the authors explicitly state that their study does not conclusively reveal the mesh's behavior in the human body. (*See* Ex. F, Shepard, JP et al., *Uniaxial Biomechanical Properties of Seven Different Vaginally Implanted Meshes for Pelvic Organ Prolapse*, 23 Int'l Urogynecology J. 613, 619 (2012) [Docket 90-1] (stating that "the experimental setup allows us to draw only preliminary conclusions about the various meshes")). Such opinions are too speculative to be deemed reliable under *Daubert*.

Moreover, with respect to mesh deformation in particular, BSC challenges Dr. Barker's opinion that BSC testing revealed approximately 35% to 52% of deformation in its mesh samples. (Ex. E, Barker Dep. (Dec. 15, 2014) [Docket 36-5], at 135:14–136:3). Dr. Barker bases this opinion on a BSC email. However, when questioned about this topic, Dr. Barker admitted that he is unsure whether this testing was done exclusively on BSC products. (*See id.* at 137:15–138:2). This deposition testimony further reveals the unreliability of Dr. Barker's methodology. BSC's motion with respect to Dr. Barker's opinions on the clinical effects of a mechanical mismatch between BSC mesh and vaginal tissue is **GRANTED**.[2]

In conclusion, BSC's Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. [Docket 36] is **GRANTED**.[3]

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[2] In their response, the plaintiffs contend that BSC does not challenge Dr. Barker's opinions "that the mesh used in the BSC products was not designed to maintain its properties when placed in the body" and that the "biocompatibility of a specific biomaterial is specific to a particular area of the body, which will respond in its own particular fashion." (Pls.' Opp'n to Def. BSC's Mot. & Mem. of Law in Supp. to Exclude Ops. & Test. of Dr. Thomas Barker, Ph.D. [Docket 68], at 11). However, this statement is incorrect. BSC addresses these two opinions in its original motion, when challenging Dr. Barker's opinions on the clinical significance of a mechanical mismatch.

[3] As for qualifications, Dr. Barker holds a Ph.D. in biomedical engineering and is currently on the faculty of a joint department within the Georgia Institute of Technology and Emory University School of Medicine. He states in his expert report that his research focuses on

> the effects of mechanical forces and tissue/material mechanical properties (e.g. stiffness) on the host response. I am trained and have extensive expertise in the evaluation of biomaterial mechanical properties, biomaterial/implant design, the foreign body host response, and human tissues under repair and fibrosis, including analyses of cell/molecular biological outcomes.

### B. Michael Thomas Margolis, M.D.

BSC seeks to exclude the testimony of Michael Thomas Margolis, M.D. Dr. Margolis is a pelvic floor surgeon and urogynecologist who offers general causation opinions in this case. (*See* Ex. A, Margolis Report [Docket 37-1], at 1–26). BSC argues that his opinions are unreliable because he failed to consider contrary scientific literature and failed to provide any scientific basis for his other opinions. Also, BSC argues that Dr. Margolis seeks to offer opinions beyond his expertise.

#### 1. BSC Argues that Dr. Margolis Failed to Consider Contrary Scientific Studies in Forming His Opinions

An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (quotations omitted). "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id.*; *see also Abarca v. Franklin Cnty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Cal. 2011) ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that

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(Ex. D, Barker Report [Docket 36-4], at 3). Dr. Barker conducted postdoctoral research focusing on "exploring the mechanisms of biomaterial associated fibrosis (e.g. the foreign body response)." (*Id.* at 2). Additionally, Dr. Barker has authored several book chapters and peer-reviewed articles. (*Id.* at 3).

I do not doubt Dr. Barker's qualifications in the field of biomedical engineering. However, I need not address them because I find Dr. Barker's opinions to be unreliable. Even if an expert is highly qualified, an analysis of the reliability of that expert's methodology is required. *See Daubert*, 509 U.S. at 597 (explaining that the Federal Rules of Evidence "do assign the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand"). Qualifications alone do not guarantee reliability. *See Hoffman v. Monsanto Co.*, No. 2:05-cv-00418, 2007 WL 2984692, at *3–5 (S.D. W. Va. Oct. 11, 2007) (excluding opinions of a "very qualified" expert because the basis for the testimony was unreliable). "[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method." *Daubert*, 509 U.S. at 590.

do not provide the support asserted." (quotations omitted)); *Rimbert v. Eli Lilly & Co.*, CIV 06-0874 JCH/LFG, 2009 WL 2208570, at *14 n.19 (D.N.M. July 21, 2009) *aff'd*, 647 F.3d 1247 (10th Cir. 2011) ("[A]n expert who chooses to completely ignore significant contrary epidemiological evidence in favor of focusing solely on non-epidemiological studies that support her conclusion engages in a methodology that courts find unreliable.").

*a. Opinion that Polypropylene Mid-Urethral Slings Are Not Safe and Effective for SUI*

BSC argues that Dr. Margolis's opinion that polypropylene mid-urethral slings are not safe and effective for the treatment of SUI is unreliable because he ignored peer-reviewed literature indicating otherwise. I do not doubt that Dr. Margolis looked at contrary studies. However, his method may be unreliable if he failed to provide a scientific basis for rejecting those studies.

In the expert materials before the court in this case, Dr. Margolis provides a sufficiently thorough explanation as to why he discounted certain literature, including discussions of bias in corporate-sponsored studies. (*See, e.g.*, Ex. A, Margolis Report [Docket 37-1], at 21; Ex. B, Margolis Dep. (Dec. 28, 2014) [Docket 73-2], at 218:9-219:20, 232:2-11). In their response, the plaintiffs also cite to articles in support of Dr. Margolis's explanation. (Pls.' Resp. in Opp'n to BSC's Mot. to Exclude the Ops. & Test. of Michael Thomas Margolis, M.D. ("Pls.' Resp. re: Margolis") [Docket 73], at 5-6). Moreover, Dr. Margolis's report particularly describes his basis for rejecting the *Nilsson* study. (Ex. A, Margolis Report [Docket 37-1], at 21). Therefore, I do not exclude Dr. Margolis's opinion based on reliability. BSC's motion with respect to this opinion is **DENIED**. Whether Dr. Margolis's reasons for rejecting certain studies are accurate or whether Dr. Margolis inconsistently applies these reasons to the literature are appropriate topics for cross-examination.

*b. Opinion Regarding the Complication Rates of Pain in Women with Polypropylene Mesh and Slings*

BSC next challenges Dr. Margolis's opinion that there is a greater than 50% complication rate of pain in women with polypropylene mesh and slings. BSC contends that he fails to provide a scientific basis for disagreeing with studies that find lower pain rates. Dr. Margolis merely discounts those studies "[b]ecause that's not what [he] ha[s] seen, read, studied, observed, and that's not biologically plausible." (*See* Ex. E, Margolis Dep. (Jan. 6, 2014) [Docket 37-2], at 239:11–13).

In his deposition, Dr. Margolis acknowledges that contrary studies exist, (*see id.* at 239:2–6), and I do not doubt that Dr. Margolis reviewed contrary studies. However, his methodology may be flawed if he does not provide an adequate explanation for why he disagrees with those studies. The plaintiffs have failed to identify such an explanation in this case. Therefore, Dr. Margolis's opinion that more than 50% of women implanted with mesh experience pain is **EXCLUDED** as unreliable. This aspect of BSC's motion is **GRANTED**.

*c. Opinions Regarding General Complication Rates in Women with Polypropylene Mesh*

BSC also challenges Dr. Margolis's general opinions that complications in women with polypropylene mesh products are high. BSC contends that Dr. Margolis disregards literature revealing single digit dyspareunia complication rates without sufficient explanation. In his deposition, Dr. Margolis discounts these studies by alleging that the complications are underreported, that the studies are inaccurate, and that the data is possibly fabricated. (*Id.* at 241:12–20). Moreover, Dr. Margolis explains that, when forming his opinion about the complication rates of a medical procedure, he "give[s] the benefit of the doubt to the patient." (*Id.* at 259:8–9). In other words, he "assume[s] the worse-case scenario" and errs on the side of

opining as to a higher complication rate to better protect a patient. (*Id.* at 259:11–19). "[G]iv[ing] the benefit of the doubt to the patient" is not a reliable, scientific basis for determining the complication rates associated with a mesh device. (*Id.* at 259:8–9). The plaintiffs have failed to demonstrate that Dr. Margolis has sufficient scientific support to opine as to these generalized statements. Therefore, this testimony is **EXCLUDED**, and this part of BSC's motion is **GRANTED**.

**2. BSC Argues That Dr. Margolis Failed to Provide Any Scientific Basis For His Other Opinions**

BSC also argues that Dr. Margolis failed to provide any scientific basis for his other opinions and that he based these opinions on his personal experience alone. The plaintiffs do not address the majority of BSC's arguments here. Instead, in a generalized fashion, they state in a paragraph that Dr. Margolis should be allowed to testify about his personal experience. (Pls.' Resp. re: Margolis [Docket 73], at 13-14). BSC interprets such a response as the plaintiffs' concession.

I decline to raise counterarguments for the plaintiffs when they have failed to address BSC's arguments in her briefing. Dr. Margolis may not solely rely on his personal observations, especially when he seeks to provide broad opinions, such as the infection rate in women with mesh. *See Daubert*, 509 U.S. at 592 (stating that Rule 702 permits "an expert [to offer] wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation" due to the "assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline"). "Proposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known." *Id.* at 590. The plaintiffs have not "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th

Cir. 1998). Therefore, the following opinions from Dr. Margolis are **EXCLUDED**: (1) that the Burch procedure is more effective than polypropylene mesh slings;[4] (2) that Xenform slings are more effective than polypropylene slings; (3) that the infection rate of polypropylene mesh is up to 100%; (4) that the complication rate of urethral obstruction is greater than 10% with polypropylene mid-urethral slings; and (5) that he has removed 10 to 15% of BSC products. These portions of BSC's motion are **GRANTED**.[5]

Unlike the above opinions, the plaintiffs appear to respond to BSC's argument concerning Dr. Margolis's opinion about a lack of scientific support for the use of mesh. In his report, Dr. Margolis opines that there is a lack of sound scientific data supporting the use of mesh in the treatment of both SUI and POP. (Ex. A, Margolis Report [Docket 37-1], at 21). First, I **EXCLUDE** this opinion with respect to POP because it is irrelevant to this SUI case.[6]

As for the reliability of this opinion with respect to SUI, BSC contends that Dr. Margolis's opinion should be excluded because Dr. Margolis contradicted himself during his deposition. In response, the plaintiffs argue that BSC misinterprets Dr. Margolis. The plaintiffs contend that Dr. Margolis merely opines that there is a lack of *long-term* data. Contradictions in testimony should be addressed on cross-examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749 (3d Cir. 1994) ("[E]valuating the reliability of

[4] *See supra* p. 7.

[5] I have previously excluded opinions (2) through (5) on reliability grounds. *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *16-18 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *10-12 (S.D. W. Va. 2014), *available at* 2014 WL 5320566; *see Eghnayem v. Boston Scientific Corp.*, __ F. Supp. 3d __, *12-13 (S.D. W. Va. 2014), *available at* 2014 WL 5461991 (addressing only opinions (3) and (5)).

[6] I note that BSC's motion only challenges this opinion with respect to SUI. (BSC's Mem. of Law in Supp. of its Mot. to Exclude the Ops. & Test. of Michael Thomas Margolis, M.D. ("BSC's Mem. re: Margolis") [Docket 38], at 12). However, the plaintiffs in their response and BSC in its reply argue as if BSC had challenged this opinion with respect to POP as well.

scientific methodologies and data does not generally involve assessing the *truthfulness* of the expert witnesses . . . ."). Therefore, I do not exclude Dr. Margolis's opinion on a lack of *long-term* data on reliability grounds.[7] Therefore, BSC's motion regarding this opinion is **GRANTED in part**, with respect to Dr. Margolis's opinion on this matter concerning POP, and **DENIED in part**, with respect to Dr. Margolis's opinion on this matter concerning SUI.

**3. BSC Argues that Dr. Margolis's Opinions are Outside His Area of Expertise**

BSC argues that Dr. Margolis offers opinions outside the scope of his qualifications on "(1) biomaterials; (2) polypropylene degradation; (3) chronic foreign body reaction; (4) adequate pore size; (5) adequate weight of polypropylene; (6) biocompatibility of polypropylene; (7) medical device design and development; and/or (8) marketing." (BSC's Mem. re: Margolis [Docket 38], at 15). In their response, the plaintiffs state that "[t]o the extent that Dr. Margolis' opinions regarding biomaterials, medical device design, development, and marketing are outside of his expertise and experience, Dr. Margolis will be instructed to limit his opinion and avoid these areas. However, Plaintiffs' [sic] stipulation is only as to these limited areas outside of his expertise." (Pls.' Resp. re: Margolis [Docket 73], at 14).

In its reply, BSC states that this concession is "unclear[.]" (BSC's Mem. of Law in Reply to Pls.' Opp'n to Def.'s Mot. to Exclude the Ops. & Test. of Michael Thomas Margolis, M.D. [Docket 82], at 5). I find that the plaintiffs' response explicitly concedes that Dr. Margolis will not offer opinions on topics 1, 7, and 8 listed by BSC. Further, the remaining topics 2 through 6 fit within at least one of the categories listed by the plaintiffs. (Pls.' Resp. re: Margolis [Docket

[7] The plaintiffs in prior cases have responded to this same challenge in a different way. *See Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *14 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *9 (S.D. W. Va. 2014), *available at* 2014 WL 5320566; *Eghnayem v. Boston Scientific Corp.*, __ F. Supp. 3d __, *11 (S.D. W. Va. 2014), *available at* 2014 WL 5461991. Instead of focusing on long-term data, those plaintiffs informed the court that Dr. Margolis never opined that there was *no* data supporting the benefits of polypropylene mesh, but just that there was no *credible* data on this subject. In those cases, I excluded Dr. Margolis's opinion because "it [was] still unclear why Dr. Margolis believe[d] th[o]se studies lack[ed] credibility." *Sanchez*, 2014 WL 4851989, at *14.

73], at 14). In terms of the concession's qualifying language—*i.e.*, to the extent these subjects are outside of Dr. Margolis's expertise, "Dr. Margolis will be instructed to limit his opinion and avoid these areas," (*id.*)—the court declines to engage in analyzing the plaintiffs' intentional ambiguity. The plaintiffs fail to provide any argument addressing how Dr. Margolis is an expert on any of the above subject matters, beyond the basic assertion that "Dr. Margolis is an established urogynecologist with years of experience with pelvic mesh products." (*Id.*). I need not make such arguments for them. Therefore, this aspect of BSC's motion is **GRANTED**.

**4. Opinions Offered by Dr. Margolis That Were Not Disclosed in His Expert Report**

Finally, BSC argues that Dr. Margolis seeks to offer opinions that were not disclosed in his expert report and that Dr. Margolis seeks to discuss materials that were not cited to in his expert report. Rule 26 requires an expert report to contain "a complete statement of all opinions the witness will express and the basis and reasons for them[.]" Fed. R. Civ. P. 26(a)(2)(B)(i). The plaintiffs do not provide a response to this argument.

First, BSC notes that Dr. Margolis's expert report does not include his opinions "on the preferred weight of mesh and immune system response[.]" (BSC's Mem. re: Margolis [Docket 38], at 17). I disagree. In his report, Dr. Margolis notes several BSC documents discussing the weight of mesh and other mesh design features. (*See* Ex. A, Margolis Report [Docket 37-1], at 11-13). Then, Dr. Margolis states:

> I agree with the statements made from Boston Scientific in its 2012 National Sales Meeting memo in that polypropylene mesh is not inert within the body, mesh shrinkage of up to 20-50% occurs, surface area is directly related to subsequent infection and complications, *a reduction in materials that come in contact with the body reduces foreign body reactions and complications*, nerve destruction by mesh leads to chronic pain, and that shrinkage of connective tissue formation (scarring and bridging) leads to complications including pain.

(*Id.* at 13 (emphasis added)). Thus, I find that Dr. Margolis's opinions on the weight of mesh and the associated complications are sufficiently disclosed. I decline to exclude his opinions on this matter on Rule 26 grounds.

BSC also argues that Dr. Margolis cited at his deposition "to a power point presentation and over 16 new articles that were not included in his report or the attachments thereto." (BSC's Mem. re: Margolis [Docket 38], at 17). BSC attaches to its motion a list of five deposition transcripts, one U.S. Patent Publication, thirty six BSC documents, and forty two scientific articles that were not included in Dr. Margolis's expert report or relied-upon list. (Ex. G, Margolis Nondisclosure List [Docket 37-2], at 1-6). Testimony on direct examination using such undisclosed sources as support for his opinions is **EXCLUDED** on Rule 26 grounds. However, the court notes that the following articles that BSC alleges were not disclosed are, in fact, included in Dr. Margolis's relied-upon list: (1) Feiner, B., et al., *Vaginal Mesh Contraction: Definition, Clinical Presentation and Management*; (2) Maher, C., et al., *Surgical management of pelvic organ prolapse in women*. (*See* Ex. A, Margolis Report, [Docket 37-1], at Appendix C). Dr. Margolis's testimony on these two articles is not excluded under *Daubert*.[8]

Therefore, I find that such aspect of BSC's motion is **GRANTED IN PART** and **DENIED IN PART**.

For the reasons stated above, I **GRANT in part** and **DENY in part** BSC's Motion to Exclude the Opinions and Testimony of Michael Thomas Margolis, M.D. [Docket 37].

**C. Jerry Blaivas, M.D.**

[8] BSC also states that any opinions that Dr. Margolis based on Laura Angelini's deposition should be excluded because the transcript "was not produced and plaintiffs' [sic] counsel would not agree to produce it." (BSC's Mem. re: Margolis [Docket 38], at 18). I decline to exclude these opinions on Rule 26 grounds. Laura Angelini's deposition is listed in Dr. Margolis's relied-upon list attached to his Rule 26 expert report. (Ex. A, Margolis Report [Docket 37-1], at Appendix C). Whether or not the plaintiffs' counsel will provide BSC with this transcript is a discovery matter.

Dr. Blaivas is a pelvic surgeon and urologist. (*See* Ex. A, Blaivas Obtryx Report [Docket 39-1], at 1).[9] The plaintiffs offer Dr. Blaivas to opine as to general causation. [10] He seeks to offer several opinions, including those related to the complications associated with polypropylene mesh slings and the Obtryx, the safety and efficacy of synthetic slings as compared to non-mesh procedures, and BSC's warnings to physicians and patients. (*See id.* at 3-5). BSC argues that Dr. Blaivas's testimony should be excluded on reliability and qualifications grounds.[11]

**1. Opinion that Polypropylene Mid-Urethral Slings Are Not Safe in the Treatment of SUI**

BSC challenges Dr. Blaivas's opinion that polypropylene mid-urethral slings are not safe in the treatment of SUI. BSC first contends that such an opinion is unreliable because Dr. Blaivas formed this opinion based on his subjective belief. However, the court need not evaluate such an argument because I **EXCLUDE** Dr. Blaivas's opinion based on BSC's second argument—that,

[9] BSC has attached several of Dr. Blaivas's expert reports to their motion, only one of which applies to this case. (*See* Ex. A, Blaivas Obtryx Report [Docket 39-1], at 1 (report which "RELATES TO: ALL BOSTON SCIENTIFIC WAVE I AND II CASES INVOLVING AN OBTRYX SLING")).

[10] Neither BSC nor the plaintiffs attach Dr. Blaivas's reliance list to his Obtryx expert report, even though Dr. Blaivas writes that, "[i]n addition to the references included herein, an Index is attached hereto and by reference made a part hereof. Please see Exhibit 'C' attached." (Ex. A, Blaivas Obtryx Report [Docket 39-1], at 22). There is an Exhibit C reliance list attached to Dr. Blaivas's expert report for the case of *Barden, et al. v. Boston Scientific Corp.*, Case No. 2:13-cv-05091, which BSC also attached to its motion in the instant case. (*See* Ex. C, Blaivas *Barden* Report [Docket 39-1], at Ex. C). However, the court is unclear as to whether that particular reliance list also applies to Dr. Blaivas's Obtryx report. Nevertheless, Dr. Blaivas's *reference* list for the Obtryx report lists several sources and studies that he considered. (*See* Ex. A, Blaivas Obtryx Report [Docket 39-1], at 17-21 (reference list for Obtryx report)). Thus, the court finds such lack of additional reliance list to have no effect on its decision here.

[11] In its motion, BSC states that it

> incorporates by reference its arguments against Dr. Blaivas's general causation opinions stated in its earlier *Daubert* motion, Case No. 2:12-cv-08633, Dkt. No. 239 and anticipates that the Court will reach the same conclusions here. Boston Scientific addresses Dr. Blaivas's general causation opinions to the extent Dr. Blaivas's testimony has highlighted additional methodological flaws and to identify opinions that the Court has excluded and should exclude again.

(BSC's Mot. & Mem. of Law in Supp. to Exclude the Ops. & Test. of Jerry Blaivas, M.D. ("BSC's Mot.") [Docket 39], at 2). However, a new expert report and new deposition testimony of Dr. Blaivas are before the court in this case. As I state above, counsel's expectations that I align with my previous rulings when faced with a different record are remiss.

in forming this opinion as a trial expert, Dr. Blaivas applied standards different than those he applies in his medical practice. In his deposition, Dr. Blaivas was confronted with a statement he had previously made in a peer-reviewed article that contradicts his safety opinion proffered in this case—namely, "The etiology of mesh sling complications is a matter of conjecture." (Ex. N, Blaivas Dep. (Dec. 15, 2014) [Docket 39-2], at 392:8-12). Dr. Blaivas explains that "I phrase my words differently in the peer-reviewed literature than I do in the legal literature because it's two different sets of rules." (*Id.* at 391:20-24). He states, "I can offer a different opinion with a reasonable degree of medical certainty than I can in the peer-reviewed literature which requires, in my judgment, a higher degree of certainty than a reasonable degree." (*Id.* at 391:14-19).

The Supreme Court has said that "[t]he objective of [the *Daubert* gatekeeping] requirement . . . is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). Although the plaintiffs attempt to persuade the court otherwise, the above deposition testimony plainly reveals that Dr. Blaivas employed less intellectual rigor in forming this opinion as an expert witness than he employs when writing studies in his field. Such admission renders Dr. Blaivas's methodology unreliable. As a result, BSC's motion with respect to this opinion is **GRANTED**.[12]

**2. Opinion on Design of Polypropylene Mesh Slings**

Next, BSC challenges Dr. Blaivas's opinion on the design of polypropylene mesh slings. (BSC's Mot. [Docket 39], at 9 (quoting Ex. A, Obtryx Report [Docket 39-1], at 6 stating, "A permanent implantable device, such as the Obtryx, Obtryx Curved and Obtryx Halo, should not have been designed for placement in a surgically contaminated field . . . .")). BSC contends that

[12] *See supra* p. 7.

this opinion should be excluded because (1) "Dr. Blaivas has no specialized training or education that qualifies him to offer opinions on product design," (2) "he has no experience implanting an Obtryx," and (3) "[t]he Court has previously held that Dr. Blaivas is not qualified to opine on product design, and the court should exclude his design opinions here." (*Id.* at 8-9 (citing court's prior order)). Although BSC's third contention is not a *Daubert* argument, I agree with BSC that Dr. Blaivas lacks qualifications to be deemed an expert in the design of a medical device. The plaintiffs contend that Dr. Blaivas's surgical experience with similar slings renders him qualified. (Pls.' Opp'n to BSC's Mot. & Mem. in Supp. to Exclude the Ops. & Test. of Jerry Blaivas, M.D. ("Pls.' Resp.") [Docket 74], at 9-10). However, this experience alone insufficiently establishes his design qualifications. Thus, his opinions related to product design are **EXCLUDED**.

**3. BSC Alleges that Dr. Blaivas Seeks to Offer Opinions Outside Area of Expertise**

BSC argues that Dr. Blaivas seeks to offer opinions on mesh shrinkage, degradation, and the Material Safety Data Sheet ("MSDS") that are outside his area of expertise. Above, I exclude Dr. Blaivas's opinion that polypropylene mid-urethral slings are not safe in the treatment of SUI on reliability grounds. Therefore, I need not address Dr. Blaivas's qualifications on shrinkage and degradation.

As for the MSDS, BSC seeks to exclude Dr. Blaivas's opinion that "[t]he polypropylene mesh used in the Obtryx, Obtryx Curved and Obtryx Halo was never meant to be implanted inside the human body per the applicable Material Safety Data Sheet ('MSDS')." (Ex. A, Blaivas Obtryx Report [Docket 39-1], at 5). The plaintiffs fail to respond to this argument, and I presume that the plaintiffs concede that Dr. Blaivas will not offer such an opinion at trial. I decline to raise counterarguments on their behalf. Thus, BSC's motion with respect to Dr. Blaivas's MSDS opinion is **GRANTED**.

**4. Specific Causation**

Although BSC argues that Dr. Blaivas's specific causation opinions should be excluded, Dr. Blaivas is not a specific causation expert in this case. (*See* BSC's Reply in Supp. of Its Mot. to Exclude the Ops. & Test. of Jerry Blaivas, M.D. [Docket 86], at 10 n.34). Therefore, BSC's motion with respect to this matter is **DENIED**.

Thus, BSC's Motion to Exclude the Opinions and Testimony of Jerry Blaivas, M.D. [Docket 39] is **GRANTED in part** and **DENIED in part**.

**D. Ron Luke, JD, Ph.D.**

The plaintiffs have indicated that they do not intend to call Dr. Luke at trial. (Disclosure Required by PTO # 121 [Docket 59]). Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Ron Luke, JD, Ph.D. [Docket 40] is **DENIED as moot**.

**E. Jimmy W. Mays, Ph.D.**

Dr. Mays is a Distinguished Professor of Chemistry at the University of Tennessee who offers general causation opinions on the following issues: (1) the chemical structure and properties of polypropylene; (2) degradation of polypropylene by thermo-oxidative processes and in vivo; and (3) the effect of in vivo degradation on the polypropylene implant. Dr. Mays's opinions are based upon his experience, knowledge, and references to scientific literature. Additionally, Dr. Mays tested the chemical and thermal properties of seven BSC pelvic repair meshes, including the Obtryx, and compared the results to four commercial isotactic polypropylene resins. Specifically, BSC takes issue with Dr. Mays's thermogravimetric analysis ("TGA"), which is a common method used for studying the thermo-oxidative stability of polymers.[13]

[13] As an initial matter, BSC attempts to incorporate by reference its *Daubert* objections to Dr. Mays's general causation opinions offered in *Sanchez v. Boston Scientific Corp.* BSC does not inform the court what these

BSC seeks to exclude Dr. Mays's opinions based on his TGA because they are unreliable and irrelevant. By way of background, Dr. Mays performed TGA on seven exemplars in the air and compared their thermo-oxidative stability to that of four commercial polypropylene resins, all of which were stabilized with anti-oxidants. (Ex. B, Mays Report [Docket 42-2], at 17). Dr. Mays also removed the anti-oxidants from one Pinnacle exemplar to examine how the mesh degraded without stabilization. (*Id.*). Dr. Mays's results showed that all of the resins degraded in a similar manner. (*Id.*). Specifically, the specimens started to degrade around 230–250 degrees Celsius and nearly completely degraded at 400 degrees Celsius. (*Id.*). Dr. Mays noted that the Lynx product showed slightly better thermal stability than the others. (*Id.*). Based on this testing, Dr. Mays concludes that anti-oxidant stabilizers delay thermo-oxidative degradation, but do not eliminate it; therefore, polypropylene will always degrade in an oxidative environment like the human body. (*Id.* at 43).

First, BSC argues that Dr. Mays's opinions should be excluded because his TGA did not replicate the in vivo environment. Specifically, BSC points out that Dr. Mays's TGA was conducted at temperatures well over 200 degrees Celsius when the human body is only approximately 37 degrees Celsius. (*See* BSC's Mem. of Law in Supp. of Its Mot. to Exclude the Ops. & Test. of Jimmy W. Mays, Ph.D. ("BSC's Mem. re: Mays") [Docket 42], at 7 ("TGA merely demonstrates that if you subject a plastic to a high enough temperature in air, it will degrade.")). In response, the plaintiffs explain that TGA is "not intended to mimic the in vivo environment," but instead "is used as a model and provides predictive information that is particularly useful for product lifetime assessments." (Pls.' Mem. in Opp'n to Def.'s Mot. to Exclude the Ops. & Test. of Pls.' Expert [Docket 71], at 7).

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objections are or attach the *Sanchez* motion. Further, the expert report offered in *Sanchez* was authored by both Dr. Mays and Dr. Gido and is not identical to the report offered in the present case. Accordingly, I will not address the objections made in *Sanchez* and instead rule solely on the issues currently before me.

Dr. Mays connects the TGA results to his ultimate conclusions regarding BSC's products in two places in his expert report:

> It should be noted that in the TGA experiments increasing temperature of the polypropylene in the presence of oxygen leads to degradation, which can be delayed but not eliminated by the presence of an anti-oxidant stabilizer packing. Polypropylene degradation also occurs isothermally inside the body. Here, too, polymer degradation may be slowed but not eliminated by the use of antioxidants.
>
> . . .
>
> Note that polypropylene always undergoes thermo-oxidative degradation in these experiments; the effect of anti-oxidant is only to delay the process. Likewise, the degradation of polypropylene exposed to an oxidative environment, such as the human body, can be delayed but not prevented through use of anti-oxidants.

(Ex. B, Mays Report [Docket 42-2], at 32, 43). The problem with these conclusions is one of fit. *See Daubert*, 509 U.S. at 591 ("Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful."). Dr. Mays produced certain results while testing polypropylene at very high temperatures. He then somehow concludes that the same results will occur inside the human body at much lower temperatures, without providing any explanation or support for his opinion. "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Id.* at 591–92. Here, Dr. Mays has failed to connect his TGA results to the pertinent inquiry, which is whether the Obtryx degrades inside the human body. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. [Docket 42] is **GRANTED**, and Dr. Mays's general causation opinions based on his TGA are **EXCLUDED**.[14]

**F. Peggy Pence, Ph.D.**

Dr. Pence works as a clinical and regulatory consultant, providing "advice, guidance, and product development services to pharmaceutical/biopharmaceutical and medical device

[14] By excluding all of Dr. Mays's TGA opinions as irrelevant, I need not address BSC's arguments regarding the anti-oxidant removal process. (*See* BSC's Mem. re: Mays [Docket 42], at 8–9).

companies in the areas of strategic planning, preclinical testing, clinical trials, design and conduct, and regulatory matters involving the [FDA]." (Ex. B., Pence Report (Nov. 10, 2014) [Docket 43-2], at 1).[15] During her career, she has accumulated knowledge about and experience with the testing requirements for medical devices; the development and content of product labeling; and the procedures necessary to comply with regulatory and industry standards, including those set forth by the FDA. (*See id.* at 1–5 (listing credentials and experiences)). In this matter, Dr. Pence offers four opinions: (1) BSC did not conduct adequate testing of its products prior to placing them on the market; (2) the products were inadequately labeled; (3) patients could not adequately consent to the surgical implantation of the products due to the misbranding; and (4) BSC failed to meet the postmarket vigilance standard of care for these products.

Although I have considered these opinions before, Dr. Pence has since updated her expert report, and, in response, BSC has refined and reevaluated its objections. Therefore, turning to these objections, I am informed—though not bound—by my previous findings.

**1. Dr. Pence's Qualifications**

I first address BSC's argument that this court should exclude Dr. Pence's opinions because she lacks the qualifications necessary to make them. BSC maintains that Dr. Pence's work as a researcher and consultant on the development of medical products does not qualify her to opine about the safety and efficacy of mesh products, as she attempts to do in her expert report. In BSC's view, without a medical degree and without experience in the development of polypropylene mesh, Dr. Pence's opinions on BSC's medical devices cannot withstand *Daubert*.

I disagree. The absence of a medical degree on Dr. Pence's curriculum vitae does not call

[15] Dr. Pence has submitted two expert reports, one focused on SUI products, (Ex. A, Pence Report (Dec. 9, 2013) [Docket 43-1]), and the other focused on POP products, (Ex. B, Pence Report (Nov. 10, 2014) [Docket 43-2]). The opinions appear to be the same in both reports, and the parties' briefings primarily refer to the most recent version. I follow suit and cite to the November 10, 2014 Report unless the arguments address an opinion stated only in the December 9, 2013 Report.

into doubt Dr. Pence's demonstrated knowledge about and experience with medical devices like those at issue. Dr. Pence has over forty years of experience in the research and development of medical devices. (Ex. B, Pence Report (Nov. 10, 2014) [Docket 43-2], at 1). Over that time, she has accumulated knowledge that is relevant to this case, such as the design of clinical trials for diseases of the female genital system, the clinical testing of novel medical devices, and the content of product labeling. Accordingly, I find that Dr. Pence is qualified to render the opinions set forth in her expert report, including her opinions about the safety and efficacy of mesh products and the sufficiency of BSC's product branding. Having found that Dr. Pence is qualified to offer these opinions, I turn to whether her opinions are relevant and reliable.

**2. General Objections**

I begin by addressing two objections that BSC raises multiple times throughout its motion, all related to the reliability of the authoritative sources underlying Dr. Pence's opinions, which include a 2006 study by the French National Authority for Health ("HAS"), the recommendations of the National Institute for Health and Care Excellence ("NICE"), and the various guidance documents drafted by the Global Harmonization Task Force ("GHTF").[16] First, BSC argues that because these studies set forth *recommendations* rather than *requirements*, they cannot serve as a reliable basis for Dr. Pence's opinions. BSC, however, has not cited any case suggesting that the binding effect of industry standards dictates their reliability. Indeed, the Seventh Circuit Court of Appeals has suggested the opposite:

> [T]he relevant question for admissibility purposes is not whether the [] guidelines are controlling in the sense of an industry code, or even how persuasive they are.

[16] The GHTF, which was conceived in 1992 and replaced by the International Medical Device Regulators Forum ("IMDRF") in 2011, represented a "partnership between regulatory authorities and regulated industry" and sought to "achieve greater uniformity between national medical device regulatory systems." (Ex. F, IMDRF, *GHTF Archive* [Docket 43-5], at 1). The European Union, United States, Canada, Australia, and Japan were the founding members, and these entities, as well as Brazil, China, Japan, and Russia, currently form the Management Committee of the IMDRF. (*Id.*). Dr. Pence relies on several GHTF "Final Documents" in reaching her opinions. (Ex. H, Pence Report (Nov. 10, 2014) [Docket 43-5], at Ex. 1).

> It is only whether consulting them is a methodologically sound practice on which to base an expert opinion in the context of this case.

*Lees v. Carthage Coll.*, 714 F.3d 516, 525 (7th Cir. 2013). Accordingly, I give no import to the non-binding nature of the HAS, NICE, and GHTF recommendations in my *Daubert* analysis and instead focus on whether Dr. Pence's reliance on these sources constitutes a "methodologically sound practice."[17]

BSC also attempts to equate GHTF standards with FDA regulations and asserts that like FDA regulations, admission of GHTF standards, which have "regulatory purpose, history, and focus," could confuse and mislead the jury. (BSC's Mot. to Exclude the Ops. & Test. of Peggy Pence, Ph.D., & Mem. in Supp. ("BSC's Mot. re: Pence") [Docket 43], at 10). Thus, BSC argues that I should exclude Dr. Pence's opinions to the extent they rely on GHTF standards, as I have done with opinions that rely on the FDA. This argument misunderstands my concern with introducing FDA evidence. If I allowed BSC to express to the jury that its product complied with FDA regulations, the jury would then view the product with the gloss of federal-government endorsement. Such a perception of the product is erroneous, given that the product was cleared for market through the FDA's 510(k) process, which "does not in any way denote official approval of the device." 21 C.F.R. § 807.97 (2012). GHTF standards, on the other hand, do not carry the same prejudicial force—the government does not promulgate them, manufacturers are not bound by them, and jurors are not familiar with them. And although the FDA appears to have had a limited role in the activities of the GHTF, *see generally* IMDRF, *GHTF organisational structure*, http://www.imdrf.org/ghtf/ghtf-structure.asp (last visited Apr. 7, 2015), that role was

[17] That said, because the guidelines that Dr. Pence relies upon are merely recommendations, Dr. Pence is prohibited from expressing to the jury that BSC was "required" to do anything under these standards, which she comes close to doing in her expert report. (*See, e.g.*, Ex. B, Pence Report (Nov. 10, 2014) [Docket 43-2], at 42 ("Premarket Clinical Data Required")).

not instrumental or definitive, and the work of the GHTF can be described without reference to the FDA. Accordingly, I find BSC's argument without merit.

Having disposed of these issues, I now address BSC's arguments with respect to Dr. Pence's opinions on premarket testing, product labeling, and post-market vigilance.

**3. Dr. Pence's Opinions on Appropriate Premarket Testing**

In her report, Dr. Pence opines:

> BSC should have performed adequate preclinical and clinical testing of the [products] prior to marketing to ensure the devices were reasonably safe for permanent implantation. By its failure to do so, BSC fell below the standard of care required of a reasonably prudent medical device manufacturer.

(Ex. B, Pence Report (Nov. 10, 2014) [Docket 43-2], at 52). In *Sanchez v. Boston Scientific Corp.*, I found this opinion reliable because Dr. Pence was able to support it with "multiple sources that stress the importance of running clinical trials before incorporating mesh materials into a surgical product," namely the HAS study and the NICE recommendations. No. 2:12-cv-05762, 2014 WL 4851989, at *34 (S.D. W. Va. Sept. 29, 2014). Here, Dr. Pence again relies on these studies, as well as GHTF standards, to support her opinion that BSC did not conduct appropriate premarket clinical trials.

Generally, BSC contends that none of the studies support Dr. Pence's opinion that BSC should have performed premarket clinical trials. My review of the exhibits, however, indicates that several guidance documents supply a basis for this opinion. For example, the GHTF's *Clinical Evaluation*, which Dr. Pence expanded on during her deposition, (Ex. G, Pence Dep. [Docket 43-5], at 192:2–197:19), states that prior to placing a device on the market, a manufacturer "must have demonstrated through the use of appropriate conformity assessment procedures that the device complies with the Essential Principles of Safety and Performance of Medical Devices," and part of this process involves analyzing—and sometimes generating—

premarket clinical data. (Ex. I, GHTF, *Clinical Evaluation* 11 (May 8, 2007) [Docket 43-5] (illustrating that if the clinical evidence is lacking, a manufacturer should "generate new or additional clinical data")). Another GHTF guidance document states that "[a]t a minimum, tests should be conducted on samples from the finished, sterilized (when supplied sterile) device." (Ex. H, Pence Report (Nov. 10, 2014) Ex. 1: Applicable Industry Standards ¶ IV [Docket 43-5] (quoting GHTF, *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles* § 11 (Feb. 21, 2008))). Additionally, although the NICE and HAS studies are not as explicit as the GHTF documents, they both emphasize the importance of clinical trials in assessing a product's safety for surgical use. (*See* Ex. F, HAS, *Evaluation of Mesh Implants Installed Through the Vaginal Approach in the Treatment of Genital Prolapse* 7 (Nov. 2006) [Docket 76-6] (emphasizing to surgeons "the necessity of using material validated by clinical trials"); Ex. G, NICE, *Surgical Repair of Vaginal Wall Prolapse Using Mesh* ¶ 1.1 [Docket 76-7] ("[T]his procedure should only be used with special arrangements for clinical governance, consent and audit or research.")).

Furthermore, all of these documents carry the indicia of reliability set forth by *Daubert*: the conclusions were reached after documented and validated testing; the results were published; and the testing was conducted through a defined methodology described in each paper. *See United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (listing the factors a court might consider when reviewing the reliability of expert testimony under *Daubert*). Therefore, I find Dr. Pence's consultation of these sources in reaching her opinion both justified and reliable.

Next, BSC argues that Dr. Pence's report lacks a "discussion of the [GHTF] standard itself" and "how Dr. Pence's application of that standard led her to form the opinions contained in her report." (BSC's Reply Mem. in Supp. of Its Mot. to Exclude the Ops. & Test. of Peggy

Pence, Ph.D. [Docket 91], at 8). Dr. Pence's deposition testimony convinces me otherwise:

> . . . I looked at the product, what was known or not known with similar products, what was known historically, what they had done historically in terms of any types of testing, what they did or did not do in terms of testing to move forward and market these products, [] the same type of analysis and methodology I apply, as I said, with my product development consulting[. B]ased on that information[, I found] that they failed in establishing a favorable benefit-risk ratio because they did not do the appropriate testing and based on the information available to them, they did not have an adequate label to appropriately advise doctors of the information they needed to know . . . . [GTHF] guidance documents state that the products must meet the essential principles of safety and performance. The product must perform as intended to have a . . . favorable benefit-risk ratio. So they needed to do the appropriate testing to establish that.

(Ex. A, Pence Dep. [Docket 76-1], at 294:15–295:16). From this testimony, I find that Dr. Pence has satisfactorily applied the GTHF standards, namely, *Clinical Evaluation* and *Essential Principles of Safety and Performance of Medical Devices*, to the facts of this case. Fed. R. Evid. 702 (providing that the court must ensure that the expert "has reliably applied the principles and methods to the facts of the case").

BSC's remaining arguments go to the weight of Dr. Pence's testimony, not its reliability, and are therefore better suited for cross-examination. In conclusion, I **DENY** BSC's motion to exclude Dr. Pence's opinion on premarket clinical testing.

**4. Dr. Pence's Opinions on the Adequacy of BSC's Product Labels**

Dr. Pence proffers two opinions regarding the labeling of BSC's products. First, she states that "BSC marketed [the Obtryx] without adequate directions for use, notably, without adequate warnings, precautions, and information for implanting surgeons and patients about the extent and likelihood of potential risks, the difficulty of mesh removal and associated morbidity should mesh removal be required, and the potential permanency and life-altering implications of certain risks of mesh removal." (Ex. B, Pence Report (Nov. 10, 2014) [Docket 43-2], at 72). Second, she states that "patients implanted with the [Obtryx] were prevented from being

adequately consented and giving fully informed consent as a result of BSC's inadequate professional and patient labeling." (*Id.* at 73). She then offers a list of warnings and risks that she believes should have been included in the products' Directions for Use ("DFU") and patient brochures. (*Id.* at 67, 71).

BSC asserts that to the extent these opinions relate to BSC's deviation from the branding requirements of the Food, Drug, and Cosmetic Act ("FDCA"), they should be excluded. I agree. As I have held several times in the course of these MDLs, expert testimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about the state tort claims than enlightenment. The jury might think that the FDA regulations *govern* warning requirements in North Carolina, whereas Dr. Pence is actually using the FDA regulations as a *model* for the contents of labeling material. *Daubert* advises courts to keep in mind the other rules of evidence when evaluating expert testimony, 509 U.S. at 595 ("Throughout, a judge assessing a proffer of expert scientific testimony under Rule 702 should also be mindful of other applicable rules . . . ."), and applying Federal Rule of Evidence 403, I find that the probative value of expert testimony on FDA requirements is substantially outweighed by the risk of jury confusion. *See* Fed. R. Evid. 403 (permitting exclusion of relevant evidence if its probative value is substantially outweighed by danger of unfair prejudice, confusion of the issues, or misleading the jury). Furthermore, simply stating that BSC did not comply with FDA regulations is a legal conclusion, not an expert opinion. For these reasons, I cannot admit Dr. Pence's testimony as it relates to the FDCA or FDA regulations. *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 755 (S.D. W. Va. 2014) (agreeing that "alleged shortcomings in FDA procedures are not probative to a state law products liability claim") (internal quotations omitted). Any opinions arising from Exhibit 1 from Dr. Pence's December 9,

2013 Report, (Ex. E, Pence Report (Dec. 9, 2013) Ex. 1: U.S. Statutory and Regulatory Framework [Docket 43-5]), are **EXCLUDED**.

This finding, however, does not result in the exclusion of Dr. Pence's opinion on product labeling altogether because, unlike previous cases, Dr. Pence has a second source of information that is unrelated to the FDA, the GHTF's *Label and Instructions for Use for Medical Devices*, which I must also consider in my analysis. The plaintiffs contend that this guidance document serves as adequate and reliable support that is "separate and distinct from FDA and FDCA regulations," and so Dr. Pence's opinion on product labeling survives BSC's *Daubert* challenge. (Pls.' Resp. in Opp'n to BSC's Mot. to Exclude the Ops. & Test. of Peggy Pence, Ph.D. ("Resp. re: Pence") [Docket 76], at 14). In response, BSC asserts that even with the GHTF document, Dr. Pence still lacks support for several of her labeling opinions. Specifically, according to BSC, *Label and Instructions for Use for Medical Devices* does not purport that a label should contain "information on severity, frequency, and/or permanency of potential adverse events" or "the difficulty of mesh removal," as Dr. Pence opines in her expert report. (BSC's Mot. re: Pence [Docket 43], at 14). I agree. The GHTF document on product labels does not state—expressly or otherwise—that manufacturers should include the severity, frequency, and/or permanency of adverse event in a warning, nor does it state that a label should qualify the difficulty of removing the device. (*See* Ex. J, GHTF, *Label and Instructions for Use for Medical Devices* 8–12 (Sept. 16, 2011) [Docket 43-5] (listing labeling content for medical devices)). Furthermore, Dr. Pence does not explain how this document could be interpreted as such. Rather, when pressed on this topic, Dr. Pence admits that the GHTF guidance document does not "get[] to that level of specificity." (Ex. G, Pence Dep. [Docket 43-5], at 261:1–3). Seeing no non-FDA grounds for Dr. Pence's opinion that BSC should have included this particular information in its labels, I find it

unreliable, and it is therefore **EXCLUDED**.[18]

With respect to Dr. Pence's remaining opinions on product labeling, BSC moves for exclusion because Dr. Pence never spoke to any physicians about this issue. An expert's failure to examine a particular source of information is not grounds for exclusion under *Daubert*, so long as the expert has other "sufficient facts or data" to support her opinion. Fed. R. Evid. 702. Here, Dr. Pence considered the GHTF's *Label and Instructions for Use for Medical Devices*, the DFU, several BSC internal documents, and other medical and scientific literature. (Ex. B, Pence Report (Nov. 10, 2014) [Docket 43-2], at 53–72). I find this collection of sources sufficient for the purposes of *Daubert*. BSC has ample grounds to cross-examine and impeach Dr. Pence at trial regarding any perceived oversights in her analysis.

**5. Opinion on Post-Market Vigilance**

In her last opinion, Dr. Pence proffers that BSC "failed to effectively monitor and manage evolving risks with its surgical mesh products for SUI and POP repair and to take appropriate action to minimize risk." (Ex. B, Pence Report (Nov. 10, 2014) [Docket 43-2], at 93). BSC argues that this opinion is not helpful to a jury because it is "premised on (1) [Dr. Pence's] review of the adverse events submitted to the FDA's MAUDE Database with respect to the devices at issue and (2) GHTF/IMDRF guidance documents." (BSC's Mot. re: Pence [Docket 43], at 16).

In arriving at these opinions, Dr. Pence exclusively considered data from the FDA's MAUDE database.[19] From the database, she compiled and analyzed the complaints and adverse

[18] BSC raises this objection only to Dr. Pence's opinions that the label should have included information on the difficulty of mesh removal and the permanency, severity, and/or frequency of adverse events. My holding is therefore limited to these specific opinions as well.

[19] "The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers." FDA, *MAUDE – Manufacturer and User Facility Device Experience*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm#fn1 (last updated Feb. 28, 2015).

event reports related to the Obtryx and concluded that BSC "fail[ed] to report serious adverse events." (Ex. B, Pence Report (Nov. 10, 2014) [Docket 43-2], at 93). As I have previously explained, BSC's communication, or alleged lack thereof, with the FDA through the MAUDE database has "no bearing on whether BSC provided adequate warnings or whether its products were defective." *Sanchez*, 2014 WL 4851989, at *36. Any opinion based on data collected in the MAUDE database, which acts as an arm of the FDA, is not helpful to the jury and is therefore inadmissible. *See* Fed. R. Evid. 702 (stating that the expert's specialized knowledge must "help the trier of fact to understand the evidence or to determine a fact in issue").

The plaintiffs retort that in using the MAUDE database, Dr. Pence "does not proffer opinions about an FDCA or FDA violation" and instead "proffers opinions that establish negligence under state tort law." (Resp. re: Pence [Docket 76], at 15). How and to what end Dr. Pence uses the data is inapposite, however, because further investigation into the MAUDE database reveals that it is unreliable, at least for the purposes of *Daubert*. The MAUDE system is a "passive surveillance system" that does not account for the "potential submission of incomplete, inaccurate, untimely, unverified, or biased data." FDA, *MAUDE – Manufacturer and User Facility Device Experience*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm#fn1 (last updated Feb. 28, 2015). As such, the data has not been reviewed for accuracy at all, let alone peer-reviewed, and the court has no way to determine the rate of error associated with Dr. Pence's use of it. In addition, given that FDA warns users that the data alone "cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices," *id.*, I can readily conclude that that application of the data to reach a scientific conclusion about a manufacturer's conduct is not generally accepted in the scientific or medical community. Because Dr. Pence's opinion on post-

market vigilance appears to be entirely based on data (or lack of data) found in the MAUDE database, I find it unreliable. Without a reliable basis, Dr. Pence's opinion on BSC's inadequate post-market vigilance is **EXCLUDED**, and BSC's motion on this matter is **GRANTED**.

**6. Final Caveat: Relevance**

I notice that several of the standards that Dr. Pence relies on were not published until after the Obtryx had entered the market in August of 2004. BSC's conduct cannot be measured against standards not existing at the time the Obtryx was being manufactured and prepared for sale. *See Redman v. John D. Brush & Co.*, 111 F.3d 1174, 1177–78 (4th Cir. 1997) ("[M]anufacturers are required to design products that meet prevailing safety standards *at the time the product is made*.") (emphasis added). Therefore, any testimony relying on standards published after August 2004 is irrelevant and not helpful to the jury. *See* Fed. R. Evid. 702 (limiting expert testimony to opinions that "will help the trier of fact to understand the evidence or determine a fact in issue"). As such, I **EXCLUDE** Dr. Pence's opinions derived solely from such sources. I trust in able counsel to tailor Dr. Pence's testimony accordingly.[20]

In sum, BSC's Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D. [Docket 43] is **GRANTED in part** and **DENIED in part**.[21]

**G. Bruce Rosenzweig, M.D.**

Dr. Bruce Rosenzweig is a urogynecologist and a professor of obstetrics and gynecology in Chicago, Illinois. The plaintiffs primarily offer Dr. Rosenzweig as an expert witness on specific causation for Ms. Mathison. (*See generally* Ex. E, Rosenzweig Report re: Mathison

[20] This court will invoke similar limitations to Dr. Pence's testimony throughout these wave cases, depending on the device at issue and when it was placed on the market, which will, of course, lead to different testimony from Dr. Pence at each wave trial. In fact, in cases involving BSC's earlier products, this limitation might prevent Dr. Pence from testifying at all, given that many of the sources she relies on to reach her opinion on premarket testing were not promulgated until 2005 or later. Again, I depend on counsel to ensure that Dr. Pence does not render opinions based on standards that did not exist when the product at issue entered the market.

[21] BSC's objection to Dr. Pence's opinions on the alleged carcinogenicity of polypropylene, uncontested by the plaintiff, is **GRANTED**.

[Docket 77-5]). In addition, Dr. Rosenzweig has served a general report about the design and labeling of the Advantage, Advantage Fit, and Lynx SUI products. (Ex. L, Rosenzweig General Expert Report [Docket 44-3]). BSC attacks these opinions as unreliable. I address BSC's objections below.

**1. Relevance of General Causation Opinions**

In his expert report concerning Ms. Mathison, Dr. Rosenzweig opines "[t]he Obtryx design is flawed as set out in the general report." (Ex. E, Rosenzweig Report re: Mathison [Docket 77-5], at 7). He also states, "[a]s discussed in my general liability report, Boston Scientific failed to include significant adverse events and risks in its [D]FU for the device . . . ." (*Id.* at 9). BSC asserts that to the extent these opinions intend to incorporate Dr. Rosenzweig's general report, it should be excluded. According to BSC, Dr. Rosenzweig's general report only discusses certain SUI products—Advantage Sling, Advantage Fit Sling, and Lynx Sling—but it does not mention the Obtryx. (*See* BSC's Mot. to Exclude the Test of Dr. Bruce Rosenzweig, M.D. & Mem. in Supp. ("BSC's Mot. re: Rosenzweig") [Docket 44], at 4 (quoting Rosenzweig General Expert Report)). Therefore, BSC argues, Dr. Rosenzweig should not be able to "bootstrap" these product-specific opinions to this case without additional explanation. (*Id.* at 5).

This argument has validity in cases where Dr. Rosenzweig attempts to apply his SUI-specific opinions to a POP plaintiff with no explanation accounting for the differences between the SUI and POP products. (*See, e.g.* Mem. Op. & Order, *Carlson v. Boston Scientific Corp.*, No. 2:13-cv-05475 [Docket 100], 34–35 (holding that without additional explanation, Dr. Rosenzweig's SUI-specific opinions cannot be arbitrarily applied to POP cases, given the important differences between POP and SUI devices)). Here, however, the product at issue is an SUI product, just like the three products referred to in Dr. Rosenzweig's general report.

Additionally, like these three products, the Obtryx is made of Advantage mesh and has an SUI-specific DFU. Wholly focusing on the differences between POP and SUI products, BSC has failed to demonstrate any material distinctions between the Obtryx and the other SUI products discussed in Dr. Rosenzweig's general report. Therefore, I cannot find that Dr. Rosenzweig's general report lacks relevance in this case.

Furthermore, I have previously found Dr. Rosenzweig's general causation opinions about the Obtryx acceptable under *Daubert*. *See Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *51 (S.D. W. Va. 2014), *available at* 2014 WL 5320566 (rejecting BSC's motion to exclude Dr. Rosenzweig's general causation opinions about the Obtryx). Dr. Rosenzweig's failure to specifically mention the Obtryx in his general report about SUI products does not convince me to abandon this ruling. Therefore, I **DENY** BSC's motion on this point.

**2. Reliability of General Causation Opinions**

In a footnote, BSC states

> In the event that this Court does allow Dr. Rosenzweig's general causation opinions for Advantage, Advantage Fit, and Lynx to apply to all other cases, such opinions should be excluded for all the reasons set forth in Boston Scientific's Motion to Exclude Dr. Rosenzweig's Testimony for those devices, filed concurrently with this Motion, and set forth in brief below.

(BSC's Mot. re: Rosenzweig [Docket 44], at 7 n.6). The motion BSC is referring to has not been filed on this docket, nor has BSC set forth its arguments "in brief below." I assume, however, that BSC intended to attach its Motion to Exclude the General Causation Testimony of Dr. Bruce Rosenzweig, M.D. ("General Causation Motion"), which it has filed in other cases within Wave 1 and Wave 2. (*See, e.g.*, *Wilkerson v. Boston Scientific Corp.*, No. 2:13-cv-4505 [Docket 31]). Acting under this assumption, I **ADOPT** my ruling on the General Causation Motion entered in *Wilkerson v. Boston Scientific Corp.* (*See* Mem. Op. & Order, *Wilkerson*, No. 2:13-cv-4505

[Docket 89], at 8–15 (granting in part and denying in part BSC's General Causation Motion)).

**3. Specific Causation Opinions**

Dr. Rosenzweig also provides a specific causation opinion for Ms. Mathison:

> It is my opinion to a reasonable degree of medical and scientific certainty, that the injuries suffered by Mrs. Mathison . . . and the majority of her post-implant medical course are a direct result of implanting the Obtryx device.

(Ex. E, Rosenzweig Report re: Mathison [Docket 77-5], at 7). BSC challenges this opinion on several grounds. First, BSC argues that Dr. Rosenzweig did not examine Ms. Mathison or speak to her treating physicians, and instead, he relied on the recorded examinations of other physicians. The Fourth Circuit Court of Appeals has held that "a physician may reach a reliable differential diagnosis without personally performing a physical examination." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001). As such, Dr. Rosenzweig's failure to physically examine Ms. Mathison does not per se render his specific causation testimony unreliable, especially when he reached his opinions by studying the records of other physicians who did examine her. *See Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 807 (3d Cir. 1997), *as amended* (Dec. 12, 1997), ("[A] physician may reach a reliable differential diagnosis without himself performing a physical examination, particularly if there are other examination results available.").

BSC next argues that Dr. Rosenzweig "repeatedly ignores and disregards the Plaintiff['s] medical records in forming his opinions." (BSC's Mot. re: Rosenzweig [Docket 44], at 8). Aside from this sweeping statement, however, BSC has presented no argument that Dr. Rosenzweig failed to adequately consider Ms. Mathison's medical records. Indeed, his report contains a thorough summary of Ms. Mathison's medical history, (*see* Ex. E, Rosenzweig Report re: Mathison [Docket 77-5], at 2–6 (providing a summary of Ms. Mathison's medical history from

2007, when she underwent implant surgery, to July 2014)), and a list of medical records that he referred to in reaching his specific causation opinion, (*see id.* at 37 (listing the relevant medical records that Dr. Rosenzweig relied upon in reaching his opinions)). Therefore, I find BSC's argument unpersuasive, and I **DENY** its motion to exclude with respect to Dr. Rosenzweig's specific causation opinion.

For the above reasons, BSC's Motion to Exclude the Opinions and Testimony of Dr. Bruce Rosenzweig, M.D. [Docket 44] is **GRANTED in part** and **DENIED in part**.

**H. Russell Dunn, Ph.D.**

Dr. Dunn is a registered professional engineer and the president and founder of Polymer Chemical Technologies, LLC, a company which focuses on process and product design issues, process and product safety, and polymer product analysis. Broadly, Dr. Dunn opines that BSC mesh devices are defective because the polypropylene mesh used in these devices undergoes oxidative degradation. BSC contends that Dr. Dunn is unqualified to opine on polypropylene pelvic mesh devices and that the testing he conducted is unreliable.

First, BSC argues that Dr. Dunn is not qualified to offer opinions concerning the design, risk management, or manufacture of polypropylene mesh devices. In support of this argument, BSC highlights Dr. Dunn's lack of experience with medical devices. In response, the plaintiffs first note that this court rejected certain *Daubert* objections to Dr. Dunn in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710–11 (S.D. W. Va. 2014). However, Ethicon did not object to Dr. Dunn's qualifications in *Huskey*, as BSC has done here. The plaintiffs also contend that the principles Dr. Dunn relies on are not specific to any kind of product but instead apply to the development of polymer products generally, which includes the development of medical devices.

"The fact that a proposed witness is an expert in one area, does not *ipso facto* qualify him

to testify as an expert in all related areas." *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 391 (D. Md. 2001) (finding an expert who is a mechanical engineer "not necessarily qualified to testify as an expert on any issue within the vast field of mechanical engineering" and listing numerous cases with similar findings). "Although Rule 702 does not require [Dr. Dunn] to be 'precisely informed about all details of the issue raised in order to offer an opinion,' *Lorillard*, 878 F.2d at 799 (citations omitted), it also does not provide an open forum for expert testimony that will not assist the trier of fact." *Wright v. Brown*, 993 F.2d 1541, *2 (4th Cir. 1993) (unpublished table decision).

BSC cites to various admissions in Dr. Dunn's deposition evidencing his complete lack of experience with medical devices outside of litigation. (*See* BSC's Mot. to Exclude the Ops. & Test. of Russell Dunn, Ph.D. & Mem. of Law in Supp. ("BSC's Mot. re: Dunn") [Docket 45], at 5–6). For example, Dr. Dunn's company, Polymer Chemical Technologies, LLC, has been involved in over 200 projects focusing on polymer product design; however, none of these projects has involved a medical device. (*See* Ex. B, Dunn Dep. [Docket 45-1], at 10:12–15). Dr. Dunn also teaches five different chemical engineering courses at Vanderbilt University; however, he has never taught a course specific to medical devices or polypropylene. (*See id.* at 12:14–13:6). Similarly, Dr. Dunn states that he has a "tremendous amount of experience" assessing risk through Failure Mode and Effects Analysis ("FMEA"), but then admits that he has "never been involved in developing an FMEA for a medical device." (*Id.* at 273:8–25.). Finally, Dr. Dunn has authored many publications throughout his career; however, not one of these publications examines medical devices or how polypropylene behaves as part of a medical device. (*See id.* at 99:13–20).

All of Dr. Dunn's opinions are premised on his belief that the polypropylene mesh in

BSC's devices will undergo oxidative degradation in the body, yet Dr. Dunn admits that he is not an expert in biomaterials or biocompatibility, and that he is not qualified to opine on the way polypropylene may affect the body physiologically. (*See id.* at 24:17–18, 152:12–14, 153:15–17). Even if Dr. Dunn relies on general engineering principles that apply to polymer products across the board, the opinions set forth in his expert report are clearly outside the scope of basic engineering. *See Shreve*, 166 F. Supp. 2d at 392 ("Unless he is to testify only to general engineering principles that any mechanical engineer would know, the engineer must possess some special skill, knowledge or experience, concerning the particular issue before the court." (quotation marks and citation omitted)). Unable to draw on some special skill, knowledge, or experience related to medical devices, Dr. Dunn's opinions, including those based on his testing of BSC products, will not be helpful to the trier of fact as required by Federal Rule of Evidence 702.

Furthermore, Dr. Dunn's testing lacks sufficient indicia of reliability because he failed to follow a written protocol or utilize a sufficiently large sample size. (BSC's Mot. re: Dunn [Docket 45], at 9-13); *see also Daubert*, 509 U.S. at 594 (stating "the court ordinarily should consider the known or potential rate of error"). I find that Dr. Dunn does not have the requisite skill, knowledge, training, education, or experience to qualify as an expert in this case, and his opinions are unreliable, and therefore, **EXCLUDED**. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. [Docket 45] is **GRANTED**.

**I. Scott Guelcher, Ph.D.**

Dr. Guelcher is a chemical engineer offered by the plaintiffs to opine on how the human body responds to polypropylene once it is implanted and the reactions that occur on the surface of the implant. Broadly, BSC contends that Dr. Guelcher's opinions on oxidative degradation

should be excluded because the testing he relies upon—testing completed by Dr. Dunn—is unreliable. As discussed more fully *supra*, because I **EXCLUDE** Dr. Dunn as an expert in this case, Dr. Guelcher's opinions—to the extent they are based on Dr. Dunn's testing—are likewise **EXCLUDED**. Therefore, BSC's Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [Docket 49] is **GRANTED**.

**J. Richard Trepeta, M.D.**

Dr. Trepeta, among other things, is a board-certified pathologist and a Fellow with the College of American Pathologists and the International Society for the Study of Vulvovaginal Disease. (*See* Ex. A, Trepeta Report [Docket 72-1], at 1–2). As part of his fellowship, he "establishes criteria and terminology for the diagnosis of vulvar and vaginal diseases." (*Id.* at 2). Dr. Trepeta also examines vulvar–vaginal pathology samples through his private practice. (*Id.*). In this case, the plaintiffs offer Dr. Trepeta to testify as an expert witness on the general pathology of vaginal mesh implantation. (*See generally id.*). BSC moves to exclude his opinions on the grounds that Dr. Trepeta lacks the qualifications to make them and that his opinions lack a reliable basis.

I have reviewed Dr. Trepeta's opinion, as well as these objections to it, several times throughout the course of this MDL. *See Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *19–24 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *15–19 (S.D. W. Va. 2014), *available at* 2014 WL 5320566; *Eghnayem v. Boston Scientific Corp.*, __ F. Supp. 3d __, *5–9 (S.D. W. Va. 2014), *available at* 2014 WL 5461991. The expert report and *Daubert* objections that were before the court in these previous cases are the same as those before the court today. (*See* Pls.' Resp. in Opp'n to BSC's Mot. to Exclude the Ops. & Test. of Richard Trepeta, M.D. ("Resp. re: Trepeta") [Docket 72], at 4

(stating that Dr. Trepeta has not changed his Rule 26 report or his opinions since the *Eghnayem*, *Tyree*, and *Sanchez* rulings)). My holdings, therefore, are likewise the same.

**1. Dr. Trepeta's Qualifications**

To testify as an expert, a witness must be "qualified . . . by knowledge, skill, experience, training or education." Fed. R. Evid. 702. Although Dr. Trepeta has an impressive background in medicine, BSC argues that his medical training does not qualify him under Rule 702 to render the opinions he sets forth in his expert reports.

*a. Properties of Polypropylene Mesh*

First, BSC objects to Dr. Trepeta's opinion testimony on the properties of polypropylene mesh. In his general report, Dr. Trepeta opines about mesh degradation, mesh contraction, and mesh migration. He states that "[d]egradation occurs as either fragmentation of the mesh or oxidation [of the mesh] release[s] chemical components from the mesh into surrounding tissues," and "[m]esh contraction and shrinkage cause the mesh to be significantly decreased in its physical size." (Ex. A, Trepeta Report [Docket 72-1], at 5). BSC asserts that Dr. Trepeta is not qualified to put forth these opinions because he is not a material scientist, biochemist, or biomedical engineer. Furthermore, he has no training in polymer science or biomedical engineering and has not performed mechanical or chemical testing of mesh products.

In making this argument, however, BSC downplays Dr. Trepeta's knowledge, training, and experience as a clinical pathologist. In general, a clinical pathologist "will be knowledgeable in the areas of chemistry, hematology, microbiology, . . . serology, immunology, and other special laboratory studies." 33 Am. Jur. *Trials* 467 § 17 (1986); *see also* Coll. of Am. Pathologists, *CAP Fact Sheet*, http://www.cap.org/apps/docs/laboratory_accreditation/international_cap_fact_sheet.pdf (last visited Apr. 3, 2015) ("[Clinical pathologists] are involved

in a broad range of disciplines, including surgical pathology, cytopathology, . . . clinical chemistry, microbiology, immunopathology, and hematology."). Dr. Trepeta's thirty years of experience as a clinical pathologist therefore demonstrates sufficient knowledge to provide expert testimony about the chemistry and surgical pathology of materials like transvaginal mesh. Moreover, Dr. Trepeta has knowledge of and experience with pelvic mesh explants in particular, having examined fifty explant samples over the past five years. (Ex. A, Trepeta Report [Docket 72-1], at 2). Given Dr. Trepeta's knowledge and experience as an anatomical and clinical pathologist, I find him qualified to testify about mesh degradation, mesh shrinkage, and mesh migration, and I therefore **DENY** BSC's motion in this respect.

*b. The Human Clinical Response to Polypropylene Mesh*

Second, BSC objects to Dr. Trepeta's testimony on the human clinical response to mesh implants. Dr. Trepeta opines that the "human body's pathological response to implantation of polypropylene mesh as well as the inherent physical properties of the mesh cause permanent injuries resulting in distortion of the pelvic architecture, sexual dysfunction, persistent pain, scarring, and alteration of bowel and bladder function." (*Id.* at 6). BSC contends that Dr. Trepeta is not qualified to present this opinion because Dr. Trepeta does not treat patients for these conditions and has limited familiarity with the symptoms of SUI and POP. In short, BSC argues that Dr. Trepeta is not a gynecologist, obstetrician, urogynecologist, or a surgeon, and as a result, Dr. Trepeta's opinions about the clinical response to mesh should be excluded.

As I explained in *Sanchez*,

> Dr. Trepeta's extensive experience and knowledge in the field of pathology qualify him to submit these opinions. Part of pathology involves reaching a diagnosis through "clinical and pathologic correlation." (*See* [Trepeta Dep.] at 11:10–14). Dr. Trepeta frequently engages in this process by providing clinical consultations to physicians, which require him to examine clinical information (through specimens, reports, or physician findings) and reach a pathologic

> diagnosis about a patient. (*See id.*). Dr. Trepeta applied this pathologic process in reaching his conclusions about the human clinical responses to polypropylene vaginal mesh. He examined fifty pathology samples from mesh removals and opines that he observed injuries "consistent with the pathological process of tissue response and/or injury due to polypropylene." (Trepeta General Report [Docket 86-1], at 2). He also compared medical literature to these observations and concluded that his pathological findings "are well described in the published literature." (*Id.*). Dr. Trepeta's understanding and application of the pathologic process qualify him to opine on the causal relationship between transvaginal mesh implantation and tissue response.

2014 WL 4851989, at *20. Therefore, I **DENY** BSC's motion on this point.

**2. The Reliability and Relevance of Dr. Trepeta's Opinions**

As stated previously, an expert's opinion is admissible if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. BSC raises two objections to the reliability and relevancy of Dr. Trepeta's opinion testimony, and I address each of these objections below.

*a. Reliability of Dr. Trepeta's Methodology*

BSC contends that Dr. Trepeta's method of using pathology reports to formulate his opinions is unreliable. Dr. Trepeta used various resources to reach his expert opinion. First, Dr. Trepeta has studied over fifty mesh explant samples in his private practice. Dr. Trepeta received these samples from physicians about once a month over the past five years. (Ex. B, Trepeta Dep. [Docket 72-2], at 71:8–13). He examined these samples under a microscope, identified any abnormalities, and concluded that the samples presented injuries "consistent with the pathological process of tissue response and/or injury due to polypropylene." (Ex. A, Trepeta Report [Docket 72-1], at 2). Second, Dr. Trepeta studied the medical literature on mesh implantation and determined that his pathological findings correspond with the published research on mesh erosion and exposure in the vaginal wall. (*Id.* at 2–3). Third, Dr. Trepeta reviewed twenty-four pathology reports that he received from the plaintiffs' counsel and ascertained that "the pathology reports of excised Boston Scientific Products . . . are consistent"

with the acute, sub-acute, and chronic categories of the disease process. (*Id.* at 4).

BSC's strongest objection to Dr. Trepeta's methodology focuses on this third source of information. BSC argues that the twenty-four pathology reports were unreliable because: they were "hand-picked by Plaintiffs' counsel"; Dr. Trepeta only relied on seventeen of the twenty-four reports; and Dr. Trepeta did not review the medical records of any of the probed patients. (BSC's Mot. to Exclude the Ops. & Test. of Richard Trepeta, M.D. & Mem. in Supp. [Docket 50], at 5–7). The plaintiffs respond that these pathology reports only supplemented Dr. Trepeta's opinion and that the main thrust of Dr. Trepeta's opinion comes from his review of fifty mesh explants over the past five years and from his study of medical literature. Moreover, the plaintiffs argue that BSC's chosen expert, Dr. Badylak, agreed that review of pathology reports of vaginal tissue taken from polypropylene explants is an accepted method for reaching a pathologic conclusion on tissue response to polypropylene. (Resp. re: Trepeta [Docket 72], at 4–5).

The fact that each side's pathologist accepts this practice suggests that it is accepted by the general community of pathologists. *See Daubert*, 509 U.S. at 594 ("Widespread acceptance can be an important factor in ruling particular evidence admissible . . . ."). But Dr. Trepeta's review of the pathology reports still has a fatal deficiency in that it lacked standards to govern the process of selecting the sample of pathology reports to be evaluated. *See id.* (listing as a factor in evaluating an expert's opinion the "existence and maintenance of standards controlling the technique's operation"). The plaintiffs do not explain how or why they chose these twenty-four reports for Dr. Trepeta's review, and without such an explanation, I have no way of assessing the potential rate of error or the presence of bias. *See id.* (stating that the "court ordinarily should consider the potential rate of error"). I confronted a similar situation in *Lewis v. Ethicon, Inc.* and excluded the expert opinion on hand-selected explant samples because "[t]here

are no assurances that [plaintiffs' counsel] did not opportunistically choose samples while ignoring others that might have weakened or disproved [the expert's] theories." No. 2:12-cv-4301, 2014 WL 186872, at *8 (S.D. W. Va. Jan 15, 2014). Here, I similarly have no way to ensure that the plaintiffs' counsel did not provide Dr. Trepeta with only those pathology reports that tended to strengthen, rather than refute, Dr. Trepeta's opinions. Accordingly, Dr. Trepeta's opinions derived from his review of the twenty-four pathology reports are **EXCLUDED**.

*b. Litigation Driven*

Finally, BSC argues Dr. Trepeta's opinions are unreliable because they are litigation driven. On the contrary, Dr. Trepeta has largely based his opinions on his professional experience with mesh pathology samples examined during his practice. (Ex. A, Trepeta Report [Docket 72-1], at 2; *see also* Ex. B, Trepeta Dep. [Docket 72-2], at 71:6–23 (explaining that over the past five years of his thirty-year practice, he has examined about fifty mesh explants that physicians had sent to him)). This work took place outside of this litigation. Thus, I find that Dr. Trepeta's opinions are not litigation-driven and **DENY** BSC's motion on this point.

In conclusion, Dr. Trepeta's general causation opinions are admitted, apart from his opinions based on the pathologic reports selected by the plaintiffs' counsel for his review, which are excluded. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Dr. Trepeta [Docket 50] is **GRANTED in part** and **DENIED in part**.

**K. Vladimir Iakovlev, M.D.**

Dr. Iakovlev is an anatomical pathologist and director of Cytopathology at the Department of Laboratory Medicine at St. Michael's Hospital in Toronto, Canada. Dr. Iakovlev offers both general and specific causation opinions with regard to the body's response to mesh from a pathologic perspective. BSC argues that Dr. Iakovlev's general causation opinions should

be excluded because he relies on specimens other than Ms. Mathison's. BSC also argues that Dr. Iakovlev's specific causation opinions should be excluded because he did not review the pathology for this particular plaintiff, Ms. Mathison.

**1. General Causation**

BSC contends that this court should "exclude Dr. Iakovlev's opinions on specimens other than each plaintiff's." (BSC's Mot. to Strike and Exclude the Ops. & Test. of Vladimir Iakovlev, M.D. [Docket 55], at 4). Dr. Iakovlev's general causation opinions are based largely on his examination of the mesh explant samples in his personal data pool. (*See* Ex. 2, Iakovlev Report [Docket 55-2], at 2, 5). However, Dr. Iakovlev provides no information on how the mesh explants were chosen or prepared for examination. Dr. Iakovlev testified that plaintiffs' counsel provided approximately 70% of the transvaginal mesh explants, but he does not know how those explants were chosen or what methodology counsel employed. (Ex. B, Iakovlev Dep. [Docket 78-3], at 38:12–39:21). Dr. Iakovlev "has given no explanation as to whether [his] is a representative sample size or how he chose the particular explants analyzed." *Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 186872, at *8 (S.D. W. Va. Jan. 15, 2014). "Therefore, I have no information as to the 'potential rate of error' inherent in [his] observations." *Id.* (citing *Daubert*, 509 U.S. at 594).

In response, the plaintiffs contend that Dr. Iakovlev's methodology is sound because it has been subjected to the publication and peer-review process. This past year, Dr. Iakovlev published two articles in peer reviewed journals about his mesh explant research. *See* Vladimir V. Iakovlev, et al., *Pathology of Explanted Transvaginal Meshes*, 8 Int'l J. Medical, Health, Biomedical and Pharmaceutical Engineering No. 9 (2014); Robert Bendavid, et al., *Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and its Morphologic Background*

*in the Etiology of Post-Herniorrhaphy Pain*, 5 Int'l J. Clinical Med. 799, 799–810 (2014). However, "[p]ublication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability," and is not dispositive. *Daubert*, 509 U.S. at 593–94. In his most recent deposition, Dr. Iakovlev does not explain how the explant samples were chosen and neither do these articles. Therefore, despite publication, the court's concerns with regard to the data pool remain. Likewise, upon review, I find the plaintiffs' remaining arguments to be without merit. Accordingly, BSC's motion on this matter is **GRANTED**, and Dr. Iakovlev's general causation opinions based on his data pool are **EXCLUDED**.

**2. Specific Causation**

It is unclear whether Dr. Iakovlev intends to offer a specific causation opinion in this case because the court has not been provided with an expert report from Dr. Iakovlev specific to Ms. Mathison. Regardless, BSC's Exhibit 1 indicates that Ms. Mathison's case is one where Dr. Iakovlev did not review any pathology. (Ex. 1 [Docket 55-1], at 4). In *Eghnayem v. Boston Scientific Corp.*, I found Dr. Iakovlev's specific causation opinions reliable based on his "morphological differential diagnosis," which included an examination of the plaintiff's explanted mesh. __ F. Supp. 3d __, *46 (S.D. W. Va. 2014), *available at* 2014 WL 5461991. In this case, there is no evidence that Dr. Iakovlev examined Ms. Mathison's explanted mesh or performed a physical examination. Assuming Dr. Iakovlev seeks to offer specific causation opinions, such opinions are not sufficiently reliable under *Daubert* and are thus **EXCLUDED**.

In conclusion, BSC's Motion to Strike and Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [Docket 55] is **GRANTED**.

## V. The Plaintiffs' *Daubert* Motions

In this case, the plaintiffs seek to limit or exclude the expert opinions of Drs. Lonny S. Green, Christine Brauer, Gary L. Winn, Stephen Spiegelberg, and Stephen Badylak.

**A. Lonny S. Green, M.D.**

Dr. Green is a board certified urologist whose "practice is largely focused on the treatment of female urinary incontinence" and who has "extensive experience" with the Obtryx. (Ex. B, Green Report [Docket 46-2], at 1). Dr. Green opines that mid-urethral slings, like the Obtryx, are the standard of care in the treatment of SUI. The plaintiffs seek to exclude Dr. Green's expert opinions on the following subjects: (1) adequacy of the DFU; (2) FDA 510(k) clearance; and (3) physical properties of polypropylene.

I have reviewed Dr. Green's opinions, as well as these objections, previously in this MDL. *See Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *70-72 (S.D. W. Va. 2014), *available at* 2014 WL 5320566. The expert report and *Daubert* objections that were before the court in *Tyree* are largely the same as those before the court today. My holdings, therefore, are likewise the same.

**1. Obtryx DFU**

First, the plaintiffs argue that Dr. Green is not qualified to offer opinions on the Obtryx DFU because he has never written a DFU and could not describe the general requirements for a DFU during his deposition. In response, BSC contends that Dr. Green does not need to be a warnings or regulatory expert "to offer competent, helpful testimony on the subject of whether Boston Scientific adequately warned of the risks and complications the plaintiff alleges." (Mem. in Opp'n to Pls.' Joint Mot. to Limit the Ops. & Test. of Lonny Green, M.D. ("BSC's Opp'n re: Green") [Docket 64], at 4).[22]

[22] I reject BSC's contention that my ruling in *Tyree* is "distinguishable and inapposite here," (BSC's Opp'n re: Green [Docket 64], at 7), given that Dr. Green seeks to offer expert opinions in this case that are nearly identical to

Author and astronomer, Carl Sagan, popularized the aphorism, "Absence of evidence is not evidence of absence." Carl Sagan, *The Demon-Haunted World: Science as a Candle in the Dark* 213 (1996). Sagan's aphorism illustrates the logical fallacy that a premise is not necessarily true merely because it has yet to be proven false. Instead, there is often insufficient investigation and information to come to a conclusive determination. Sagan's musings are relevant here because the plaintiffs have challenged the defendant's attempt to offer experts seeking to opine on the adequacy of product warnings. In the past, I allowed a doctor to testify that the DFU was inadequate because it failed to warn against risks the doctor observed in his or her own practice. In contrast, now I must determine whether the same kind of doctor is instead qualified to offer his expert opinion that the warnings were in fact adequate. There is a clear distinction. The plaintiffs' experts observed certain risks and complications in their practice and then sought to opine that those risks should have been included in the product warnings. In the present case, BSC's experts have observed certain risks and complications in their practice, which are warned of in the DFU, and therefore deduce that there are no other possible risks or complications that should have been included. The plaintiffs' experts address a discrete risk which they have personally observed, while BSC's experts' opinions attempt to encompass all possible risks, none of which they have personally observed. Accordingly, I **FIND** that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included risks he has observed in his own practice.

In his expert report, Dr. Green discusses the risks of pelvic surgery and states that "[a]ll of the aforementioned potential complications are adequately warned of in the [DFU] for the

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those previously offered and excluded. Dr. Green is free to testify that complications he has observed are in fact warned of in the DFU. What he cannot do is use these observations to subsequently conclude the DFU was adequate.

Obtryx sling." (Ex. B, Green Report [Docket 46-2], at 11). Dr. Green fails to address the significance of complications he has not seen in his practice, and which are not warned of in the DFU. In his deposition, Dr. Green admits he has never drafted a DFU for a medical device or pharmaceutical. (Ex. D, Green Dep. [Docket 46-4], at 532:2-16). Although Dr. Green indicates he has "expertise" in the process of writing patient handouts warning against drug complications, his experience appears to be limited to his review and distribution of these handouts, rather than contribution to the drafting. (*Id.*). Accordingly, I **FIND** that Dr. Green is not qualified to opine on the adequacy of product warnings, and therefore, his opinions related to the Obtryx DFU are **EXCLUDED**.

**2. FDA 510(k) Clearance**

Next, the plaintiffs contend that Dr. Green is not qualified to opine on the FDA 510(k) clearance process. BSC concedes that Dr. Green will not offer opinions on the FDA 510(k) clearance process. Accordingly, the plaintiffs' motion is **GRANTED**. Furthermore, I have repeatedly held that the probative value of FDA evidence is substantially outweighed by the risk of jury confusion. Therefore, to the extent Dr. Green seeks to offer other expert opinions on the FDA, such opinions are likewise **EXCLUDED**.

**3. Physical Properties of Polypropylene**

***a. Qualifications***

Lastly, the plaintiffs argue that Dr. Green is not qualified to opine that the Obtryx does not shrink, contract, degrade, or cause systemic infections because he is not a pathologist and "has never looked at any mesh (explanted from a patient or otherwise) under a microscope." (Pls.' Mot. & Mem. of Law in Supp. of Their Joint Mot. to Limit the Ops. & Test. of Lonny Green, M.D. (Pls.' Mem. re: Green") [Docket 46], at 9). I disagree. A lack of personal

experience performing pathology research on polypropylene explants does not necessarily render Dr. Green unqualified under Rule 702 to offer opinions on the suitability of the Obtryx device. An expert may be qualified by "knowledge, skill, experience, training, or education[.]" Fed. R. Evid. 702. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989).

Dr. Green has performed almost 3,000 sling procedures, and his clinical practice has "largely focused on the treatment of female urinary incontinence" over the last twenty years. (Ex. B, Green Report [Docket 46-2], at 1). Further, Dr. Green cites numerous studies and academic papers throughout his expert report to support his opinion that the Obtryx is both safe and effective. I therefore **FIND** that Dr. Green is qualified to offer the opinion that the Obtryx mesh does not shrink, contract, degrade, or cause systemic infections.

***b. Reliability***

The plaintiffs also argue that Dr. Green "has not utilized any method – let alone a reliable method – to reach the conclusions outlined in his report." (Pl.'s Mem. re: Green [Docket 46], at 10). Dr. Green plans to testify that he has not seen "evidence of polypropylene degradation, systemic infection, or other unexpected reactions" and that "[t]he Obtryx has proven to be safe and efficacious for the treatment of female SUI." (Ex. B, Green Report [Docket 46-2], at 10). District courts have "considerable leeway" in applying *Daubert's* reliability factors. *Kumho Tire*, 526 U.S. at 152. Here, Dr. Green's opinion is partially based on the fact that he has observed minimal complications in his clinical practice. Obviously, this type of opinion is not subject to testing or peer review. Additionally, Dr. Green explains that his "clinical experience with the Obtryx is on par with the findings in [the] studies" he cites throughout his expert report. (*Id.* at

9). Therefore, I **FIND** Dr. Green's clinical experience and review of the scientific literature are sufficiently reliable bases in forming this particular opinion.

For the above reasons, the plaintiffs' Motion to Exclude the Opinions and Testimony of Lonny Green, M.D. [Docket 46] is **GRANTED IN PART** and **DENIED IN PART**.

**B. Christine Brauer, Ph.D.**

Dr. Brauer is the President of Brauer Device Consultants, LLC, where she provides consulting services to the medical device industry regarding FDA regulatory requirements. The plaintiffs seek to exclude both of Dr. Brauer's expert reports filed on November 21, 2014. The first report ("FDA report") focuses on the FDA regulatory requirements for surgical devices, and the second report ("supplemental report") focuses on industry standards that a manufacturer of a medical device must meet. (*See* Ex. 2, Brauer Dep. [Docket 88-2], at 8:13–20). "Anticipating that the Court will adopt its prior rulings and exclude FDA evidence here," BSC does not contest the plaintiffs' motion with regard to the FDA report. (BSC's Resp. in Opp'n to Pls.' Mot. to Exclude or Limit the Test. of Expert Christine Brauer, Ph.D. [Docket 65], at 1). In *Sanchez v. Boston Scientific Corp.*, I ruled as follows:

> I have repeatedly and thoroughly considered the admissibility of the FDA's 510(k) process, and I have consistently found that the 510(k) process does not relate to safety or efficacy. *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, at 753–56 (S.D. W. Va. 2014). Therefore, the parties may not present evidence regarding the 510(k) clearance process or subsequent FDA enforcement actions. This is consistent with prior rulings by this court. *See, e.g.*, *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 U.S. Dist. LEXIS 102699, at *22 (S.D. W. Va. July 23, 2013) ("The FDA 510(k) process does not go to safety and effectiveness and does not provide any requirements on its own. Basically, it has no operative interaction with state tort laws.") (internal reference omitted); Order, *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195 (S.D. W. Va. July 1, 2013), [Docket 309], at 3–4 ("Under United States Supreme Court precedent, the FDA 510(k) process does not go to whether the product is safe and effective . . . . Because the FDA 510(k) process does not go to whether the [mesh] products are safe and effective and the 510(k) process does not impose any requirements on its own, the 510(k) process is inapplicable to this case. This evidence is excluded under Federal Rule of

> Evidence 402 as irrelevant, and under Rule 403 for the reasons previously stated, including the very substantial dangers of misleading the jury and confusing the issues."); Mem. Op. & Order, *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195 (S.D. W. Va. June 27, 2013) [Docket 302], at 3–4 (holding that evidence regarding the 510(k) process and enforcement should be excluded under Rule 403); Mem. Op. & Order, *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201 (S.D. W. Va. May 12, 2014 [Docket 223], at 1 ("This is not the first time I am confronted with determining the admissibility of evidence relating to marketing clearance under the FDA's 510(k) process . . . In all previous cases, I excluded all evidence relating to the 510(k) process because it does not go to the safety and efficacy of medical devices and because of the potential to mislead and confuse the jury."). Accordingly, I **FIND** that Dr. Brauer's opinions should be excluded in their entirety.

No. 2:12-cv-05762, 2014 WL 4851989, at *36–37 (S.D. W. Va. Sept. 29, 2014). Accordingly, the plaintiffs' motion with regard to Dr. Brauer's FDA report is **GRANTED**, and her opinions set forth in that report are **EXCLUDED**.

With regard to the supplemental report, the plaintiffs contend that it "is nothing more that [sic] her FDA Report under a different cloak." (Pls.' Reply in Supp. of Pls.' Mot. to Exclude or Limit the Test. of BSC's Expert Christine Brauer, Ph.D. [Docket 88], at 4). Therefore, in the plaintiffs' view, Dr. Brauer's supplemental report should be excluded for the same reasons her FDA report was previously excluded, given that the two reports are "substantially identical." (Pls.' Mot. & Mem. to Exclude or Limit the Test. of BSC's Expert Christine Brauer, Ph.D. [Docket 47], at 2). I agree. Reading the two reports side by side, it appears that Dr. Brauer "supplemented" her report by removing references to the FDA and substituting the term "industry standard" instead. For example, in her supplemental report, Dr. Brauer states: "It is an industry standard for a manufacturer of certain new or modified medical devices to demonstrate that its new device is substantially equivalent to another legally marketed device, and is as safe and effective as other similar devices prior to marketing in this U.S." (Ex. 3, Brauer Report [Docket 65-1], at 4). This "industry standard" clearly describes the FDA 510(k) process, which

Dr. Brauer admitted in her deposition. (*See* Ex. 2, Brauer Dep. [Docket 88-2], at 43:7–18 ("Q: I'm talking about this one sentence . . . That's the 510(k) process; correct? A: That is the 510(k) process.")).

Also, Dr. Brauer states that medical devices are grouped into three categories, which she labels as "Low-Risk," "Moderate Complexity and Risk," and "Complex, High Risk." These "industry standard" categories perfectly align with the three regulatory classes established by the Medical Device Amendments, another fact Dr. Brauer admitted. (*See id.* at 48:13-–9 ("Q: The low-risk medical devices are Class I devices. The moderate complexity and risk medical devices are Class II devices; correct? A: For most products, they probably would fit in that way, yes.")).

BSC contends that Dr. Brauer's industry standard opinions do not require presenting FDA evidence to the jury because the industry standards are broader than FDA regulations. However, Dr. Brauer explained that FDA regulations are part of industry standards, and, therefore, any evidence with regard to industry standards would require reference to the FDA, whether it is disguised or not. (*See id.* at 34:13–23 ("A: When you do it with industry, you want to make sure that your regulatory requirements are met, but also that certain customer needs are met. So there's a little different of a slant, but it's still the primary same content. Q: So in both ways you're trying to comply with FDA regulations? A: In part. In both ways you're trying to comply with FDA regulations because that's part of it.")).

Furthermore, although she cites a few standards issued by the International Organization for Standardization ("ISO"), including ISO 13485, in her supplemental report, when asked about additional standards during her deposition, Dr. Brauer could not recall any specific standards, other than ISO 13485. (*Id.* at 35:15–21). And when pressed on whether there is an ISO standard that requires manufacturers to submit adverse events to the FDA, Dr. Brauer was unable to

articulate an identifiable ISO standard to support her premise. (*See id.* at 46:18–47:1 ("Q: It says that it's an industry standard to submit certain reports to adverse events to the FDA. A: That's correct. Q: So there's no actual standard that says that; correct? A: I don't believe it's that specifically stated in the ISO standard.")). Dr. Brauer's inability to identify an applicable standard renders her opinion unreliable. *See Lasorsa v. Showboard: The Mardi Gras Casino*, No. 07-4321, 2009 WL 2929234, at *5 (D.N.J. Sept. 9, 2009) ("Without a reliable, objective basis for [expert] testimony, stemming from identifiable industry standards, codes, publications or training, it must be precluded under Rule 702.")

Dr. Brauer's deposition testimony reveals that her true area of expertise is the regulatory field, which is why she was originally retained to write a regulatory report. (*See id.* at 12 ("I believe the first contact was regarding FDA regulation of medical devices.")); *see also Pension Comm. of Univ. of Montreal Pension Plan v. Banc of Am. Sec., LLC*, 691 F. Supp. 2d 448, 476 (S.D.N.Y. 2010) (finding an expert's opinions with regard to industry standards unreliable when not "ground[ed] in his knowledge of the custom and practice of the industry"). There is far too much overlap between Dr. Brauer's FDA report and supplemental report to avoid a regulatory mini-trial, which I have repeatedly and consistently held would confuse and mislead the jury. Accordingly, the plaintiffs' Motion to Exclude the Opinions and Testimony of Christine Brauer, Ph.D. [Docket 47] is **GRANTED**, and Dr. Brauer's opinions are **EXCLUDED** in their entirety.

**C. Gary L. Winn, Ph.D.**

Dr. Winn is a professor in Industrial and Management Systems Engineering in the Safety Management program at West Virginia University. Dr. Winn offers expert "opinions with regard to the nature and purpose of Material Safety Data Sheets (MSDS) generally, and specifically as to the MSDS for the polypropylene used by [BSC] in the manufacture of its pelvic mesh

products." (Ex. A, Winn Report [Docket 48-1], at 1). The plaintiffs argue that Dr. Winn's opinions should be excluded entirely, consistent with this court's decisions in *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *63 (S.D. W. Va. 2014), *available at* 2014 WL 5320566, and *Eghnayem v. Boston Scientific Corp.*, __ F. Supp. 3d __, *61 (S.D. W. Va. 2014), *available at* 2014 WL 5461991, because his expert report is identical to the reports filed and excluded in those two cases.[23] In response, BSC contends that it "should be allowed to offer Dr. Winn's testimony and opinions to rebut MSDS related evidence presented by the Plaintiffs at trial." (BSC's Mem. in Opp'n to Pls.' Combined Mots. to Exclude the Ops. & Test. of Gary L. Winn, Ph.D. [Docket 66], at 17). Specifically, BSC points to the transcripts from *Tyree* and *Eghnayem* where the plaintiffs' experts testified about the MSDS. (*Id.* at 15–16).

BSC has not presented any new arguments to convince me that Dr. Winn is warranted as an independent expert. However, I acknowledge the potential need for rebuttal testimony based on what the plaintiffs present at trial. Accordingly, I **RESERVE** ruling on the admissibility of Dr. Winn's expert opinions for trial.

**D. Stephen Spiegelberg, Ph.D.**

Dr. Spiegelberg is the president and co-founder of Cambridge Polymer Group, Inc., where he directs a team of scientists who perform contract research, analytical testing, and

[23] In *Tyree*, I ruled as follows:

> In his expert report, Dr. Winn describes (1) the development of the hazard communication standard; (2) the standardization of the content of MSDSs; and (3) uses of MSDSs in the field. Dr. Winn concludes that raw polypropylene is not hazardous based on anecdotal evidence involving other MSDSs; and therefore, the 2004 Chevron Phillips MSDS is extraneous. Although I believe that the warning provided in the MSDS is relevant, I do not believe an expert is required to discuss MSDSs generally or the issue of whether polypropylene requires an MSDS because of its hazardous nature. A narrative review of the history and development of MSDSs and who uses them in the field is not helpful to the jury. The pertinent issue is that the MSDS contained a warning (Medical Application Caution) allegedly not heeded by BSC, not that an MSDS itself existed. This warning from the supplier could have taken any form. Accordingly, I **FIND** that Dr. Winn's opinions regarding MSDSs should be excluded in their entirety.

2014 WL 5320566, at *63; *see also Eghnayem*, 2014 WL 5461991, at *61 (quoting *Tyree*).

device development for the biomedical and polymer communities. Broadly, Dr. Spiegelberg opines that BSC's pelvic mesh products "are appropriate for their intended use in design and manufacture." (Ex. B, Spiegelberg Report [Docket 54-2], at 4). The plaintiffs object to the following general causation opinions offered by Dr. Spiegelberg: (1) general causation opinions regarding the position statements of medical organizations; (2) any matters related to the FDA clearance process; (3) opinions regarding the presence of black specks in BSC's mesh; and (4) opinions based on Fourier Transform Infrared Spectroscopy ("FTIR") and Energy Dispersive Spectrometry ("EDS"). I address these objections in turn.

**1. Position Statements**

First, the plaintiffs argue that Dr. Spiegelberg's opinions regarding position statements should be excluded because (1) they are not contained in his expert report; (2) he is not qualified to offer such opinions; and (3) he lacks any reliable methodology. In response, BSC states that Dr. Spiegelberg does not offer opinions regarding position statements in either his expert report or his most recent deposition. Upon review, I agree with BSC that Dr. Spiegelberg does not in fact offer the opinions the plaintiffs seek to exclude. Accordingly, the plaintiffs' motion with regard to position statements is **DENIED as moot**.

**2. FDA**

Next, the plaintiffs contend that Dr. Spiegelberg is unqualified to opine on the FDA 510(k) clearance process and that such opinions should be excluded as irrelevant. In response, BSC concedes that Dr. Spiegelberg will not offer opinions on the FDA 510(k) clearance process. Accordingly, the plaintiffs' motion with regard to the FDA is **GRANTED**. BSC limits its concession by arguing that Dr. Spiegelberg is qualified to opine on ISO standards based on his "extensive experience in the field of medical device analysis and design." (BSC's Resp. in Opp'n

to Pls.' Mot. to Exclude the Ops. & Test. of Dr. Stephen Spiegelberg, Ph.D. [Docket 75], at 6). I agree. Dr. Spiegelberg's current work focuses on medical device development and consultation. (*See* Ex. B, Spiegelberg Report [Docket 54-2], at 2). He is also the Task Force Chairman for ASTM standards involving the cleanliness of biomedical devices and characterization methods for polymers. (*Id.* at 3). Consulting on the development of new medical products requires familiarity with the applicable industry standards. Therefore, to the extent Dr. Spiegelberg intends to opine on ISO standards without referencing the FDA, I find him qualified to do so. Accordingly, the plaintiffs' motion with regard to Dr. Spiegelberg's qualifications is **DENIED**.

**3. Black Specks**

Next, the plaintiffs argue that Dr. Spiegelberg's opinions regarding black specks in BSC's mesh are unfounded and unreliable. In his expert report, Dr. Spiegelberg states: "I have reviewed information suggesting 'black [specks] may appear in the polypropylene. These 'black [specks] are actually reflections of light on the curves of the mesh when pictures are taken, rather than inclusions or defects in the mesh." (Ex. B, Spiegelberg Report [Docket 54-2], at 12). Dr. Spiegelberg elaborated on this conclusion in his deposition:

> Q: And if I remember – do you remember what your opinion was in regard to black specks?
>
> A: I do.
>
> Q: Can you tell me?
>
> A: The black specks that I observed in the meshes were not black specks per se, as in terms of inclusions, rather were just reflections that are often inherent in circular surfaces.
>
> Q: And did you perform independent testing to verify that?
>
> A: Yes, I did.
>
> Q: And could you describe that to me?

> A: You take the mesh and place it in an optical microscope, and then rotate the mesh under the optical microscope and see if the black specks move or disappear, which they did.

(Ex. D, Spiegelberg Dep. [Docket 75-1], at 17:22–18:14). The plaintiffs contend that Dr. Spiegelberg's findings are unreliable because he did not review the photographs supplied by the plaintiffs' expert, Dr. Dunn, nor did he take his own photographs. However, in his deposition, Dr. Spiegelberg testified that he did review Dr. Dunn's photographs. (*Id.* at 19:15). And whether Dr. Spiegelberg took his own photographs does not sufficiently undermine the reliability of his analysis here. Challenges to Dr. Spiegelberg's ultimate conclusion with regard to the nature of the black specks are better suited for cross-examination. Accordingly, the plaintiffs' motion with regard to black specks is **DENIED**.

**4. FTIR/EDS**

Last, the plaintiffs seek to limit Dr. Spiegelberg's general causation opinions based on his FTIR and EDS testing. However, the plaintiffs also state that Dr. Spiegelberg's "admissions regarding the limitations of these techniques may also be grounds for cross-examination," and seek only "qualification or explanation of the limitations inherent to these techniques" in order to avoid misleading or confusing the jury. (Pls.' Mot. & Mem. in Supp. of Mot. to Exclude the Test. & Ops. of Dr. Stephen Spiegelberg, Ph.D. [Docket 63], at 11). The plaintiffs will have the opportunity to adequately highlight these limitations at trial upon cross-examination. Accordingly, the plaintiffs' motion with regard to Dr. Spiegelberg's FTIR and EDS testing is **DENIED**.

In sum, the plaintiffs' Motion to Exclude the Testimony and Opinions of Dr. Stephen Spiegelberg, Ph.D. [Docket 54] is **GRANTED in part** and **DENIED in part**.

**E. Stephen Badylak, D.V.M., Ph.D., M.D.**

Dr. Badylak is the Deputy Director of the McGowan Institute for Regenerative Medicine, Director of the Center for Preclinical Studies, and a full Professor with tenure with the Department of Surgery at the University of Pittsburgh. Broadly, Dr. Badylak opines that the polypropylene mesh used in BSC's pelvic mesh products is biocompatible and safe for use in the human body. The plaintiffs ask the court to exclude Dr. Badylak's (1) opinions related to the risk/benefit analysis or the safety and efficacy of BSC devices; and (2) opinions related to oxidative degradation.

**1. Risk/Benefit Analysis or Safety & Efficacy**

First, the plaintiffs contend that Dr. Badylak should be precluded from opining on the safety and efficacy of polypropylene mesh devices because he has not reviewed the applicable scientific literature and has no clinical experience using these devices. In support of her argument regarding scientific literature, the plaintiffs cite to a portion of Dr. Badylak's deposition where he "admitted" that he has not performed a "comprehensive review" of the literature related to specific BSC devices. (Pls.' Mot. & Mem. of Law in Supp. of Their Mot. to Exclude the Ops. & Test. of Stephen F. Badylak, D.V.M., Ph.D., M.D. [Docket 56], at 7). However, Dr. Badylak's expert report indicates that he reviewed more than 200 relevant scientific publications, including more than twenty publications evaluating the safety and efficacy of BSC devices. (BSC's Opp'n to Pls.' Mot. to Exclude the Ops. & Test. of Stephen F. Badylak, D.V.M., Ph.D., M.D. [Docket 63], at 8; *see also* Ex. 2, Additional Materials Considered for Expert Report [Docket 56-2], at Ex. B). Furthermore, Dr. Badylak explained that he is more familiar with the body of literature reviewing the safety and efficacy of surgical mesh generally, versus literature specific to any one device. (*See* Ex. 5, Badylak Dep. [Docket 56-5], at 98:22–25); *see also Wheeler v. John Deere Co.*, 935 F.2d 1090, 1100 (10th Cir. 1991)

(explaining that "a lack of specialization does not affect the admissibility of the opinion, but only its weight"). This explanation does not undermine his qualifications but instead clarifies his approach. If there are certain device-specific publications that Dr. Badylak failed to review in preparing his expert report, the plaintiffs are free to ask him about those publications on cross-examination.

Similarly, the plaintiffs' arguments regarding Dr. Badylak's clinical experience are also without merit. Dr. Badylak has extensive experience in the field of biomaterials, including the design of implantable surgical mesh devices. (*See* Ex. 2, Badylak Report [Docket 56-2], at 1). The qualification requirement of Federal Rule of Evidence 702 does not necessarily require specific clinical experience implanting the device at issue. *See Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989) ("One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion."); *see also Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *4–5 (S.D. W. Va. July 8, 2014) (finding expert qualified to offer general causation opinions despite his lack of specific experience with the product at issue). Accordingly, the plaintiffs' motion with regard to Dr. Badylak's safety and efficacy opinions is **DENIED**.

**2. Degradation**

Lastly, the plaintiffs argue that Dr. Badylak's opinions with regard to oxidative degradation based on the scientific literature are unreliable because he contradicted himself during his deposition by acknowledging the "phenomenon" of oxidative reactions. (*See* Ex. 5, Badylak Dep. [Docket 56-5], at 108:2–6 ("I'm aware of the literature and the discussion, I'm aware of phenomenon of oxidative changes and oxidative reactions in the body everywhere, including the surface of biomaterials such as polypropylene, so yes, I've considered that. . . . As

a matter of fact, I'm on record as saying oxidative reactions occur everywhere, including the surface of biomaterials."). However, the plaintiffs omit Dr. Badylak's subsequent testimony, where he states: "What I don't believe is that these oxidative reactions at the surface of polypropylene are resulting in the degradation that's causing further problems. There's no evidence to suggest that exists." (*Id.* at 108:11–109:15). Upon review of the deposition, I do not find Dr. Badylak's testimony sufficiently contradictory to undermine the reliability of his expert opinions. Accordingly, the plaintiffs' motion with regard to degradation is **DENIED**.

The plaintiffs' Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [Docket 56] is thus **DENIED**.

## VI. Effect of *Daubert* Ruling

I emphasize that my rulings excluding expert opinions under Rule 702 and *Daubert* are dispositive of their potential admissibility in these cases, but my rulings not to exclude expert opinions are not dispositive of their admissibility at trial. In other words, to the extent that certain opinions might be cumulative or might confuse or mislead the jury, they may still be excluded under Rule 403 or some other evidentiary rule.

## VII. Conclusion

For the reasons discussed above, my rulings on BSC's motions are as follows:

Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. [Docket 36] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Michael Thomas Margolis, M.D. [Docket 37] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Jerry Blaivas, M.D. [Docket 39] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Ron Luke, JD, Ph.D. [Docket 40] is **DENIED as moot**; Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. [Docket 42]

is **GRANTED**; Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D. [Docket 43] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Bruce Rosenzweig, M.D. [Docket 44] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. [Docket 45] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [Docket 49] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Richard Trepeta, M.D. [Docket 50] is **GRANTED in part** and **DENIED in part**; and Motion to Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [Docket 55] is **GRANTED**.

My rulings on the plaintiffs' motions are as follows:

Motion to Exclude the Opinions and Testimony of Lonny S. Green, M.D. [Docket 46] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Christine Brauer, Ph.D. [Docket 47] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Gary L. Winn, Ph.D. [Docket 48] is **RESERVED**; Motion to Exclude the Opinions and Testimony of Stephen Spiegelberg, Ph.D. [Docket 54] is **GRANTED in part** and **DENIED in part**; and Motion to Exclude the Opinions and Testimony of Stephen Badylak, D.V.M., Ph.D., M.D. [Docket 56] is **DENIED**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 6, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE